IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* DAVID M. KESTER, et al., Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, et al., Defendants.	Civil Action No. 1:11-cv-08196 (CM) **ECF CASE**

CORRECTED JOINT PRE-TRIAL ORDER

TABLE OF CONTENTS

The parties having conferred among themselves and with the Court pursuant to Federal Rule of Civil Procedure 16, the following statements, directions and agreements are adopted as the Pre-Trial Order herein.

I. NATURE OF THE CASE

This is a False Claims Act case brought by the United States, 11 Intervening States, as well as the Relator David Kester acting on behalf of 17 other States (collectively, "Plaintiffs") against Novartis Pharmaceuticals Corporation ("Novartis"). Plaintiffs allege that Novartis orchestrated two kickback schemes: one involving an iron chelation drug called Exjade, and the other involving an immunosuppressant drug called Myfortic. Both Exjade and Myfortic are manufactured and marketed by Novartis.

With respect to Exjade, Plaintiffs allege that Novartis referred Exjade patients to three specialty pharmacies – Accredo, BioScrip, and US Bioservices – and offered and paid so-called rebates to those pharmacies with a purpose of inducing the pharmacies to recommend to patients that they order Exjade refills.

With respect to Myfortic, the United States and Relator on behalf of the States allege that Novartis offered and paid five specialty pharmacies (Kilgore's, Bryant's, Baylor, Twenty Ten, and Transcript) kickbacks in the form of so-called performance rebates with a purpose of inducing those pharmacies to recommend Myfortic over a competitor drug called CellCept and over generic versions of CellCept.

Plaintiffs allege that, by orchestrating the two schemes described above, Novartis violated the Anti-Kickback Statute. Plaintiffs also allege that Novartis violated the federal and state False Claims Acts by causing the specialty pharmacies to make or use false statements and/or to submit false or fraudulent claims to Medicare and Medicaid programs and by

conspiring with the specialty pharmacies to violate the False Claims Acts. With respect to Exjade, the Intervening States further allege other state statutory and common law claims.

Plaintiffs seek damages and statutory penalties.

Novartis denies that any discounts, rebates or patient referrals to pharmacies in connection with Exjade or Myfortic violated the Anti-Kickback Statute, the federal and state False Claims Acts, or any other state laws. Novartis contends that it provided legitimate and lawful rebates to specialty pharmacies in order to encourage them to provide better patient care to their Exjade patients and to make Myfortic more accessible to kidney transplant patients.

II. JURY/NON-JURY

A. Plaintiffs' Statement

A jury has been demanded. There is no dispute as to whether the action should be tried to a jury. The Court has allocated 3 weeks for trial.

B. Defendant's Statement

Novartis estimates that it can present its case in chief as to both drugs at issue (Exjade and Myfortic) in three weeks. This estimate assumes that Plaintiffs will take the same amount of time for cross-examination of our witnesses as we take to conduct direct examination of those witnesses.

We cannot provide an estimate of the time we will need to cross-examine Plaintiffs' witnesses because we do not believe Plaintiffs have provided a true witness list. The list proposed by Plaintiff currently includes 150 witnesses, which cannot possibly be the number they intend to present at trial.

III. STIPULATED FACTS

A. Parties' Background

1. The United States, represented by the U.S. Attorney's Office for the Southern District of New York, intervened as a plaintiff in this case as to the Relator's allegations regarding Myfortic and Exjade; 11 states also intervened as to Relator's allegations regarding Exjade: California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington and Wisconsin (collectively, the "Intervening States").

2. Novartis Pharmaceuticals Corporation ("Novartis") is a pharmaceutical corporation and has its principal place of business at 1 Health Plaza, East Hanover, New Jersey 07936.

B. Exjade

3. Exjade is an iron chelator indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age or older.

4. The United States Food and Drug Administration ("FDA") approved Exjade in November 2005.

C. Myfortic

5. Novartis manufactures and distributes Myfortic.

6. Myfortic was approved by the FDA in February 2004 to prevent organ rejection in patients who have received kidney transplants.

7. Myfortic is an immunosuppressant. It is part of a class of drugs known as mycophenolic acids ("MPAs"). Myfortic is taken in pill form.

8. CellCept, manufactured by Hoffmann-LaRoche Ltd., was approved by the FDA in 1995 to prevent organ rejection in patients who have received kidney, liver or heart transplants. CellCept is taken in pill form or intravenously.

9. MPA is the active ingredient in both CellCept and Myfortic.

10. CellCept lost its patent exclusivity in or around May 2009.

11. Myfortic was available only in brand form during the time period relevant to this trial.

12. Beginning in or around May 2009, generic forms of CellCept, known as mycophenolate mofetil ("MMF"), became available on the market. Prior to approximately May 2009, CellCept was available only in brand form.

D. Medicare

13. Medicare is a federal program that provides federally-subsidized health insurance for persons who are 65 years or older or disabled, as well as for persons with certain long-term chronic healthcare needs, including end-stage renal disease.

14. Medicare provides several different types of coverage for beneficiaries. As relevant to this trial—Part B of the Medicare program provides supplemental benefits to participants to cover, among other things, physician services and certain prescription drugs; and Part D of the Medicare Program provides prescription drug benefits for Medicare beneficiaries.

15. Accredo Health Group, Inc. ("Accredo"), BioScrip, Inc. ("BioScrip"), and U.S. Bioservices Corporation ("US Bioservices") obtained reimbursement under Medicare Part D for Exjade they dispensed between January 2006 and December 2013.

16. Under Medicare Part D, the Plan Sponsor (directly or indirectly) reimbursed the pharmacy for the portion of the cost that was not covered by the beneficiary's co-pay. The Part D Plan Sponsor provided the reimbursement if and only if the pharmacy was under a Part D subcontract with the Plan Sponsor. Federal funds were used to provide a portion of the reimbursement to Accredo, Bioscrip and U.S. Bioservices for Exjade.

17. Medicare Part B—the other Medicare program that is relevant to this trial—provided reimbursement to pharmacies for transplant medications, including Myfortic and Cellcept.

E. Medicaid

18. Medicaid is a joint federal-state program that provides health care benefits for low-income or disabled families or individuals and certain other groups.

19. The States operate Medicaid programs under federal and state laws and regulations.

20. Claims paid by the States' Medicaid programs to Medicaid providers, including pharmacies, effectively use both federal and state funds. Medicaid is a federal health care program to which the AKS applies

IV. PARTIES' CONTENTIONS

The pleadings are deemed amended to embrace the following, and only the following, contentions of the parties:

A. PLAINTIFFS' CONTENTIONS

1. Novartis Violated the AKS by Giving Kickbacks to BioScrip, Accredo, and US Bio to Recommend Exjade Refills

Overview

1. The Exjade kickback scheme involved Novartis's effort to increase Exjade sales by exploiting two facts — first, Novartis controlled how patient referrals were assigned to the three pharmacies that it had picked to dispense Exjade; and, second, nurses at those pharmacies were able to develop relationships with Exjade patients and effectively influence patients' decisions about whether to order refills.

2. In 2007, Novartis recognized that the EPASS SPs could increase Exjade sales by having their staff, especially nurses, recommend that Exjade patients order refills. To induce the EPASS SPs to make recommendations, Novartis leveraged its control over Exjade patient referrals and also offered so-called "rebates" to the EPASS SPs:

a. Novartis "pushed" the pharmacies – under the threat of reducing or stopping patient referrals – to have nurses to call Exjade patients to recommend refills;

b. Novartis created a contest pitting the three EPASS SPs against each other under which, every six months, Novartis would give a larger share of patient referrals to the pharmacy with the highest refill rates; and

c. Novartis offered the pharmacies the opportunity to earn so-called "rebates" if they met the quarterly shipment goals set by Novartis based on Novartis's "national Exjade sales targets." *See infra* ¶¶ 21-60.

3. To retain their place in EPASS and in return for getting more patient referrals and for earning rebates, the EPASS SPs assigned nurses and other staff to recommend refills to Exjade patients. Specifically, nurses and other staff at the pharmacies called patients to exaggerate the danger of not taking Exjade continuously, emphasize Exjade's benefits, and downplay the severity of Exjade's side effects. *See id*.

4. Novartis willfully implemented this kickback scheme. Specifically, having sought advice from counsel, Novartis's officers knew that allocating patient referrals based on refill rates increased the risk of violating the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"). Indeed, counsel recognized this risk even though Novartis had not provided all relevant facts to counsel. Further, Novartis knew the scheme was wrongful and undermined patient care because, under Novartis's encouragement, the pharmacies provided unbalanced or medically inaccurate information and advice to Exjade patients in order to obtain more refill orders. *See infra* ¶¶ 61-75.

Exjade Approval, Novartis's Post-Approval Obligations, and Label Changes

5. Novartis manufactures and markets Exjade, an iron-chelation drug. In the United States, Novartis's oncology business unit is responsible for Exjade sales and marketing. (Testimony of, *inter alia*, Chee, Jolley, Ng).

6. In 2005, Novartis sought FDA approval for Exjade under an accelerated process established pursuant to 21 C.F.R. § 314.510 ("Subpart H approval"). Novartis also requested approval for a "broad label" for Exjade that was not limited to just beta-thalassemia and pediatric sickle cell disease patients, but also included other patient populations like adult sickle cell patients and myelodysplastic syndrome ("MDS") patients. (Testimony of, *inter alia*, K. Miller, E. McGee, and R. Boehm).

7. In November 2005, Novartis obtained FDA approval for Exjade on an accelerated basis for use in treating "chronic iron overload due to blood transfusions … in patients 2 years of age and older." (Testimony of, *inter alia*, K. Miller and E. McGee).

8. Novartis viewed Exjade's indication in the 2005 label as a "broad label," which allowed Novartis to market Exjade to patient populations – such as MDS and adult sickle cell patients – who had lower medical urgency and less excess iron and/or received blood transfusions on an intermittent (rather than regular) basis. *See, e.g.*, PX-1141, PX-811.

9. After launching Exjade, Novartis closely monitored the makeup of new and existing Exjade patients, including the numbers and percentages of MDS and adult sickle cell patients. To take just one example — in December 2005, senior U.S. Oncology executives at Novartis asked for data concerning the number of MDS patients, and they were informed that 38% of new Exjade patients were designated as MDS patients. *See, e.g.*, PX-1048.

10. Because Novartis sought and obtained accelerated FDA approval for Exjade, Novartis was required to fulfill certain post-approval obligations, including to submit all Exjade

promotional materials to FDA for review at least 30 days before their use and to conduct post-approval clinical studies regarding Exjade's efficacy, side effects, and long-term benefits and risks.

11. Shortly after it obtained FDA approval for Exjade, Novartis wanted to distribute Exjade promotional materials that would discuss the dangers of iron overload and suggest that patients benefit from taking Exjade continuously. The FDA, however, repeatedly rejected proposed Exjade promotional materials that purported to describe the dangers of iron overload because those statements implied that Exjade could broadly "enhance survival in patients" or "is effective in the prevention or delay of 'multiorgan damage'" when neither "has [] been demonstrated by substantial evidence." To give one example — in December 2005, the FDA notified Novartis that making claims such as "regardless of etiology, transfusional iron overload increases morbidity and mortality," "inadequately chelated patients are at increased risk of serious health problems and decreased survival," or "iron overload can lead to multiorgan damage" in discussing Exjade were "overstatement[s] of efficacy." (PX-1201)

12. Once Novartis began marketing Exjade, patients using Exjade reported side effects that were both more frequent and more severe than what had been identified during the pre-approval studies. By late 2006, Novartis became aware of this problem and the fact that side effects were a major factor in why doctors or patients decided to discontinue Exjade therapy. *See*, *e.g.*, PX-1157.

13. Due to the frequency and severity of side effects reported, Novartis was required by FDA to update the Exjade labels in December 2006, April 2007, December 2007, October 2008, and, finally, January 2010.

14. The January 2010 label change for Exjade included a black box warning. Specifically, Exjade label was revised to add, among others, the following warnings and directions:

- Exjade was contraindicated for patients with "high-risk MDS" who have limited life expectancy and for patients with low kidney function;
- "Exjade may cause" kidney failure, liver failure, and gastrointestinal hemorrhage, and that "[i]n some reported cases these reactions were fatal;"
- "In postmarketing experience, there have been reports of serious adverse reactions, some with a fatal outcome, in patients taking Exjade therapy, predominantly when the drug was administered to patients with advanced age … Most of these deaths occurred within six months of Exjade initiation"; and
- Exjade posed increased "risk of toxicity" when it "is given to patients with low iron burden or with serum ferritin levels that are only slightly increased." (PX-833)

EPASS and Simple Steps

15. To distribute Exjade, Novartis created a closed distribution network called EPASS, consisting of three specialty pharmacies – BioScrip, Accredo, and US Bioservices (together, the "EPASS SPs") – and a data hub called LASH. In creating EPASS, Novartis recognized the federal healthcare programs, especially Medicaid, would be a major source of coverage for Exjade. (Testimony of, *inter alia*, P. Pochtar)

16. Within EPASS, approximately half of the patients were designated for a specific pharmacy based on payor requirements or physician/patient preferences. The other patients were not so designated, and Novartis directly controlled how LASH would assign those "undesignated patients" among the pharmacies.[1] (Testimony of, *inter alia*, E. Chee and R. Boehm)

17. Before launching EPASS, Novartis sought and obtained legal advice concerning how to allocate patient referrals. Outside counsel advised Novartis to allocate the undesignated patient referrals equally among the three pharmacies because unequal allocation could raise legal

[1] In some cases, the payor, physician, or patient required or preferred the use of two of the pharmacies. Those patients also were classified as "undesignated" within EPASS.

concerns. Novartis decided to follow that advice at first and initially allocated patient referrals on a rotational basis equally to BioScrip, Accredo, and US Bioservices. *See, e.g.*, PX-1757 and testimony of S. Goldfarb.

18. In November and December 2005, Novartis signed contracts with the three EPASS SPs. Under those contracts, each SP was entitled to a rebate payment from Novartis – ranging from $13 to $110 – for each Exjade shipment they dispensed. (Testimony of, *inter alia*, R. Corvese and P. Pochtar)

19. When it began marketing Exjade, Novartis planned to implement a compliance and persistency program – called "Simple Steps" – that was separate from EPASS. Novartis's 2005 contracts with the EPASS SPs provided that the pharmacies would encourage patients to enroll in Simple Steps. *See, e.g.*, PX-2725; PX-363.

20. Novartis's plan for Simple Steps involved sending Exjade-branded materials to patients. As part of its post-approval obligations to the FDA, Novartis was required to submit those materials to the FDA for review. (Testimony of, *inter alia*, P. Ng)

In February 2007, Novartis and BioScrip Agreed on a Plan for BioScrip to Recommend Refills to Exjade Patients in Return for Retaining Patient Referrals

21. In early 2007, Novartis's U.S. oncology unit faced significant shortfalls in Exjade sales as compared to the sales targets established by Novartis's global management. To take one example – in January 2007, actual Exjade sales were about 20% lower than the budgeted sales targets for that month. *See, e.g.*, PX-568/569.

22. Novartis viewed low refill rates and high patient discontinuations as major factors contributing to the lower Exjade sales. Novartis also knew and understood that patients frequently did not order refills because their physicians were concerned about Exjade's side effects, because the patients could not tolerate the side effects, or because the patients or their

physicians concluded that the benefits of Exjade did not outweigh its side effects and other downsides. *See, e.g.*, PX-1157/1158.

23. By early 2007, Novartis also had developed an "Exjade Scorecard" for tracking refill rates for different patient cohorts at each of the EPASS SPs. In other words, the Exjade Scorecard allowed Novartis to compare how much the EPASS SPs were able to keep patients ordering Exjade. *See, e.g.*, PX-1153.

24. In early February 2007, Novartis saw that the refill rates for Exjade were lower at BioScrip as compared to Accredo and US Bioservices. Novartis decided that, to increase Exjade sales, it would place BioScrip under a "performance improvement plan" (the "BioScrip PIP"). *See, e.g.*, PX-1157/1158.

25. Specifically, at a meeting on February 7, 2007, Novartis advised BioScrip that, unless it implemented a plan for getting patients who stopped ordering Exjade refills to restart ordering and increasing its refill rates, Novartis would stop assigning undesignated patients to BioScrip or, possibly, eject it from EPASS. *See, e.g.*, PX-1233.

26. Novartis managers and BioScrip executives understood that ejecting BioScrip from EPASS or a reduction in the number of undesignated patients assigned to BioScrip would mean significant lost sales and lower rebate payments for BioScrip. For example, on February 7, 2007, Scott Friedman, a BioScrip senior vice president, told his subordinates that being ejected from EPASS would cost BioScrip $60 million in annual Exjade sales and that "no other specialty contract, no other mail order contract, nothing, is more important" to BioScrip than keeping its place in EPASS. (PX-1441).

27. To retain the patient referrals and rebate payments, BioScrip presented an "action plan to improve Exjade patient retention" to Novartis on February 15, 2007. (PX-3172)

28. As part of that plan, BioScrip told Novartis that it would make more calls to patients. BioScrip also told Novartis that it would assign a nurse to contact patients who had stopped ordering Exjade refills to recommend that they "restart" and call other patients to recommend that they continue to order refills. More specifically, BioScrip showed Novartis how it would make the recommendations, including – to give one example – to tell Exjade patients that they should continue taking Exjade because "untreated excess iron kills after inflicting injury to a variety of body organs" and because "hemochromatosis is completely reversible." (PX-3173)

29. As Novartis knew, the FDA had already concluded that such claims about Exjade were "overstatements of efficacy" because they were "not supported by substantial evidence." But, rather than advising BioScrip not to make such claims, Novartis encouraged BioScrip to implement its "action plan" and gave BioScrip 45 days to demonstrate the effectiveness of its efforts to recommend Exjade refills to patients. *See, e.g.*, PX-2022.

30. Between February and April 2007, Novartis closely tracked the results of BioScrip's efforts to convince patients to restart on Exjade and to recommend refills to its Exjade patients. The reports from BioScrip corroborated Novartis's understanding that the most common reasons for stopping Exjade therapy were because doctors and patients were concerned about side effects and effectiveness of the drug. *See, e.g.*, PX-1508.

31. By mid-April 2007, Novartis recognized that BioScrip's efforts had yielded the results Novartis wanted in terms of convincing patients to restart Exjade and increasing refill rates. Accordingly, Novartis agreed to allow BioScrip to remain in EPASS and not to reduce the level of patient referrals. *See, e.g.*, PX-2022.

32. In April 2007, FDA required Novartis to update the Exjade label to include warnings about hepatic adverse reactions that could be life-threatening. Novartis did not suggest that BioScrip update its nurse call scripts to reflect that label change. Instead, BioScrip continued to use a set of call scripts that emphasized the importance of taking Exjade continuously and claimed that Exjade's side effects usually resolve on their own. (Testimony of, *inter alia*, N. Edwards).

33. After April 2007, Novartis and BioScrip continued to work closely to get patients to keep ordering Exjade. BioScrip used under-qualified staff to make recommendations, and did not require its staff to gather information necessary to allow them to provide informed counseling to patients. Importantly, BioScrip showed Novartis additional examples of how its nurses recommended that patients order Exjade refills. Those included telling patients taking Exjade would provide long term benefits to their health and advising an adult sickle cell patient that, if she stopped taking Exjade, it could cause more frequent and more severe relapses of her sickle cell condition. *See, e.g.*, PX-2217, 2218 and testimony of C. Johnson, A. Haddad, and C. Daniels.

34. Novartis knew that claims about Exjade's long-term benefits and risks could not be substantiated and that there was no scientific basis for linking the use of Exjade to the frequency or severity of relapses of sickle cell condition. Yet, rather than advising BioScrip about those inappropriate claims, Novartis encouraged BioScrip to expand its Exjade program to include more patients. In early 2008, Novartis increased the amount of per-shipment "rebate" it paid BioScrip by 50% – from $13 to $20 – to "provide [BioScrip] with the resources to maintain the full High Touch program." (PX-2737).

In Late 2007, Novartis Decided to Rely on the EPASS SPs, Instead of Simple Steps, to Generate Refill Orders for Exjade

35. Novartis saw BioScrip's efforts to use nurses to recommend Exjade refills to patients continued to generate higher refill rates. By July 2007, BioScrip had leapfrogged the other two pharmacies to first place in terms of refill rates among new Exjade patients. (Testimony of, *inter alia*, E. Chee and R. Jolley)

36. By that time, Novartis also recognized that it would not be able to implement its plans for Simple Steps due to delays with obtaining regulatory approval for materials. *See, e.g.*, PX-1042.

37. In or about August 2007, Novartis decided to rely on the EPASS SPs, rather than Simple Steps, to keep patients on Exjade and generate refill orders. Specifically, Novartis concluded that because it had successfully "implemented a high-touch nurse counseling program at [BioScrip]," it should "roll [] out" similar programs "in January 2008 to all pharmacies." *Id.*

38. The "high-touch nurse program" that Novartis told Accredo and US Bioservices to implement involved having those pharmacies assign one or more nurses to make a series of calls to Exjade patients. Novartis wanted the pharmacies to use nurses because Novartis understood that the nurses, as compared to pharmacists, were better at developing relationships with Exjade patients and earning their trust. That, in turn, made the nurses more effective at influencing Exjade patients to stay on the drug and order more refills. *See, e.g.*, PX-2011.

39. More specifically, Novartis expected the pharmacy nurses to focus on two topics – emphasizing the dangers of iron overload and counseling Exjade patients to "manage" their side effects – because Novartis knew that those types of advice were effective at influencing patients to order more refills. Novartis also told the pharmacies that the nurse calls to patients should be "front load[ed]." (PX-1187)

40. To induce Accredo and US Bioservices to set up the "high touch nurse programs" based on its designs, Novartis again relied on its control over patient referrals. Specifically, Novartis told these pharmacies that, unless they increased their refill rates by having nurse programs, they could receive fewer undesignated patient referrals or stop receiving such referrals altogether. (Testimony of, *inter alia*, F. Padron and W. Hinshaw)

41. In response to the threat of losing patient referrals, which were highly valuable, Accredo and US Bioservices implemented nurse programs for Exjade based on what Novartis wanted.

42. US Bioservices agreed to assign up to three nurses to call patients to recommend they keep taking Exjade. Further, in December 2007, US Bioservices showed Novartis sample call scripts. According to the scripts, the nurses would tell MDS patients that not taking Exjade could result in or aggravate their diabetes and tell parents of pediatric sickle cell patients that not taking Exjade could cause their children to become infertile. *See, e.g.*, PX-2020.

43. Similarly, Accredo agreed to Novartis's demand and assigned a nurse to call Exjade patients using a call script that told patients it was "extremely important" for them to take Exjade continuously and that not taking Exjade could cause damages to their organs. Novartis not only received a copy of the Accredo call script, but its managers also met directly with Accredo personnel about how to discuss Exjade with patients. *See, e.g.*, PX-806.

44. As Novartis knew, the call scripts given to the nurses at Accredo and US Bioservices included claims about Exjade that the FDA had deemed to be overstatements of efficacy. Yet, rather than advising the pharmacies to remove those claims, Novartis encouraged the pharmacies to make those claims to patients. For example, in February 2008, senior

executives at Novartis emphasized to Accredo the importance of having the nurse call as many patients as possible using the script. *See, e.g.*, PX-1187.

In 2008, Novartis Launched the Pay for Performance Scheme

45. As it was pressuring Accredo and US Bioservices to implement "high-touch nurse programs" to increase refill levels, executives at the U.S. oncology unit at Novartis also began to develop an overall scheme to incentivize all three EPASS SPs to keep refill levels high and aid Novartis with meeting internal sales targets.

46. This scheme, which Novartis literally called "Pay for Performance," had two elements. First, Novartis would link the volume of patient referrals to the level of refill orders the EPASS SPs generated; and, second, Novartis would offer additional "performance rebates" to the pharmacies based on whether they generated enough Exjade orders to help Novartis meet its "National Exjade Sales Target ($)."

47. In 2008, Novartis discussed the "Pay for Performance" scheme with the EPASS SPs. Specifically, Novartis obtained agreements from all three pharmacies to a plan to shift the allocation of undesignated patient referrals every six months, with 60% of the referrals going to the pharmacy with the highest refill rates in the Exjade Scorecard and 20% to each of the other two pharmacies.

48. Novartis implemented the "Pay for Performance" scheme in two phases — it began paying "performance rebates" to the EPASS SPs in the second quarter of 2008 and announced the patient allocation aspect of the scheme in October 2008.

49. As Novartis planned, the "Pay for Performance" scheme led to a competition among the EPASS SPs to be or remain "number one" and thus obtain more patient referrals. This, in turn, led the EPASS SPs to focus on generating refill orders, rather than patient care. (Testimony of, *inter alia*, N. Edwards, B. White, and J. Williams)

50. Each pharmacy, for example, established shipment goals or quotas for their Exjade staff to meet. To meet those goals or quotas, the managers at the EPASS SPs pushed their staff to pressure patients to order Exjade refills even when the patients did not want or need the drug. To give just one example — in 2010, BioScrip instructed its Exjade team to "n[o]t let the patient say[] they have 2-3 weeks supply on hand off the phone until we order their next refill." (PX-0787).

51. Further, even as the frequency and severity of Exjade's side effects became more widely known, the EPASS SPs continued to emphasize the benefits of Exjade while downplaying its side effects. After FDA required Novartis to add a "black box warning" to the Exjade label in January 2010, for example, Accredo required its nurse to follow a call script that warned patients not taking Exjade could cause "stroke or death," but did not warn patients about the serious, potentially life-threatening, side effects of taking Exjade. Similarly, in early 2010, BioScrip made no change to its nurse call script, which continued to emphasize the importance of staying on Exjade while advising patients that Exjade's side effects usually resolve by themselves. (Testimony of, *inter alia*, N. Edwards, B. White, J. Williams, K. Miller, C. Johnson, A. Haddad, and C. Daniels)

52. Although Novartis and the EPASS SPs all understood that patient referral allocation and the "performance rebates" were part of an overall incentive scheme, Novartis decided not to disclose the patient referral aspect of the scheme in its written agreements with the pharmacies. *See*, *e.g.*, PX-4023.

53. Specifically, although Novartis created and signed numerous amendments to its contracts with the EPASS SPs, none of those documents contains any reference to the patient allocation aspect of the scheme. Indeed, Novartis decided to conceal this aspect of the scheme

from the contracts even after Accredo asked Novartis in 2009 that their written agreement reference patient allocation.[2] *See id*.

54. As part of the "performance rebates" aspect of the "Pay for Performance" scheme, Novartis paid rebates if EPASS SPs exceeded quarterly shipment goals set by Novartis. But, instead of informing the SPs of the quarterly goals in advance, Novartis often provided the goals when the quarters were nearly over. *See, e.g.*, PX-766.

55. After setting up this unlawful scheme, the Exjade business team sought to exploit Novartis's relationships with the EPASS SPs to have the pharmacies recommend Exjade to physicians. This included recommending dosage increases and recommending "Desferal conversion," *i.e.*, switching patients from desferal to Exjade. For example, in 2008, Novartis had BioScrip develop a program for the nurse and other staff at BioScrip contact physicians' offices to recommend "a dosage increase." In 2010, Novartis asked both BioScrip and Accredo to implement a "Desferal conversion strategy" that involved identifying patients receiving desferal and then contacting physicians' offices to recommend that the patients be switched to Exjade. *See, e.g.*, PX-2852, PX-2308, PX-2351.

56. In spring 2010, Novartis revised the "performance rebate" aspect of the "Pay for Performance" scheme. Instead of using quarterly shipment goals, Novartis offered the EPASS SPs "rebates" based on the number of refills ordered by individual patients. *See, e.g.*, PX-4023.

57. Novartis made the change to incentivize the pharmacies to recommend refills to patients irrespective of whether the patients needed Exjade in light of factors such as their

[2] Novartis bears the burden of proof as to any of its affirmative defenses, including, but not limited to, any invocation of an AKS safe harbor. Plaintiffs reserve the right to rebut any such invocation. For example, to the extent that Novartis asserts the "performance rebates" it offered the EPASS SPs were subject to the "discount" safe harbor, such a claim fails in light of, *inter alia*, the failure to disclose the patient allocation scheme in its written contracts with the EPASS SPs.

underlying disease states, their overall medical conditions, how they reacted to Exjade, and how frequently they were due to receive blood transfusions.

58. After implementing the "Pay for Performance" scheme, Novartis continued to use its ability to withhold patient referrals as a means to pressure the EPASS SPs. For example, after BioScrip failed to satisfy Novartis's expectations in terms of Exjade purchases in late 2010, Novartis placed BioScrip under a "performance enhancement plan" and stopped assigning undesignated patients to BioScrip between April and June 2011. To regain the patient referrals, BioScrip had to intensify its efforts to recommend that patients who had stopped ordering Exjade refills to restart. *See, e.g.*, PX-767.

59. In late 2011 and early 2012, Novartis conducted a review of whether to continue to incentivize the EPASS SPs to call patients. Specifically, Novartis was concerned this led to too many adverse event reports for Exjade. *See*, *e.g.*, PX-3953.

60. Novartis, therefore, decided to stop the Pay for Performance scheme, which took effect in March 2012. Upon the discontinuation of the scheme, Accredo immediately discontinued the nurse program. From the time that Novartis initiated the BioScrip PIP to the time Novartis discontinued Pay for Performance, the EPASS SPs submitted tens of thousands of Exjade claims to Medicare and Medicaid. *See infra* ¶ 118.

Novartis Willfully Orchestrated the Exjade Kickback Scheme

61. Novartis knew that it was required to comply with the AKS in marketing and distributing Exjade. At all relevant times, Novartis's own Ethics and Compliance Policies gave notice to Novartis personnel of the need to comply with the AKS whenever a drug involved federal healthcare programs like Medicare or Medicaid. Further, even before launching Exjade, Novartis knew that Medicaid would be a major payor for the drug.

62. Novartis knew that how it allocated patient referrals among the EPASS SPs presented legal risks. In 2005, Novartis sought legal guidance on this issue and followed such guidance to implement an equal distribution of the undesignated patient referrals. Yet, when Novartis threatened to reduce the flow of patient referrals to BioScrip in February 2007 in an effort to make BioScrip generate more refills, Novartis chose not to seek legal guidance about whether it should deviate from the existing arrangement. Indeed, Novartis chose not to seek legal guidance even though executives within the Oncology Managed Markets group had raised concerns about making threats to BioScrip about reducing patient referrals. (Testimony of, *inter alia*, K. Olsen and S. Goldfarb)

63. As early as November 2007, when Novartis was first considering the "Pay for Performance" scheme, in-house counsel raised concerns that creating a "contest" for patient referrals could be deemed a "kickback" arrangement. (Testimony of, *inter alia*, F. Padron)

64. In April 2008, in-house counsel advised the Exjade business team at Novartis not to shift patient allocation based on refill or "compliance" rate based on concerns about AKS compliance. (Testimony of, *inter alia*, E. McGee)

65. The Exjade business team, however, was not satisfied with the response. They enlisted a senior executive – the then-head of the hematology franchise – to "challenge" the legal advice. (Testimony of, *inter alia*, E. McGee)

66. In May 2008, Novartis in-house counsel sought advice concerning patient referral allocation from an outside attorney at the Reed Smith law firm, and the outside attorney advised Novartis to "keep criteria [for allocation] away from compliance." (PX-1193) Based on that advice, in-house counsel advised the Exjade business team not to use compliance or refill rate as

the basis for allocating patient referrals, but instead to use measures like patient satisfaction and time-to-ship. *See, e.g.*, PX-1884.

67. The Exjade business team again refused to accept the legal advice from in-house and outside counsel. They claimed that refill or compliance rate was a true reflection of patient care. However, the business team did not advise either in-house counsel or outside counsel that the EPASS SPs in fact were offering advice and information to Exjade patients that the FDA had deemed to be "overstatement[s] of efficacy." Novartis executives knew that making such claims undermined patient care. Further, withholding this information from counsel undermined counsel's assessment of the legal risks associated with the patient allocation scheme. (Testimony of, *inter alia*, E. McGee and J. Metro)

68. In the summer of 2008, outside counsel continued to warn Novartis about the increased risk associated with allocating patient referrals based on refill or compliance rates. *Id*.

69. Senior executives at Novartis (including an officer of Novartis), however, decided that the benefits it would reap from pitting the EPASS SPs against each other for patient referrals outweighed the legal risk of violating the AKS. Thus, in October 2008, Novartis notified the pharmacies that it would create the contest for patient referrals and obtained agreements from the pharmacies to the scheme. *See, e.g.*, PX-3255.

70. In addition of being aware that its conduct could violate the AKS, Novartis also understood that it was wrongful to direct the EPASS SPs to assign nurses to recommend Exjade refills to patients. Novartis knew that the pharmacies created scripts for nurses to use when they discussed Exjade therapy with patients. Some Novartis personnel reviewed these scripts, but they also did not follow company policy and subject the scripts to formal review to ensure they

presented information fairly and in a balanced way. (Testimony of, *inter alia*, M. Mignogna and E. Epstein)

71. The Exjade business team avoided having the nurse call scripts reviewed because they were aware that the scripts used by Accredo, BioScrip, and US Bioservices contained unbalanced and medically inaccurate advice about Exjade. Specifically, the Exjade business team knew that each pharmacy was giving patient information or advice that the FDA had determined to "overstate[]" the efficacy of Exjade or "minimiz[e] the risks" of Exjade. Indeed, it was against internal policy for Novartis to support or encourage pharmacies making such statements to patients.

72. The Exjade business team also avoided documenting the true nature of the "pay for performance" scheme in any of Novartis's written contracts with the EPASS SPs because they knew it was wrongful. Specifically, the contracts between Novartis and the pharmacies contained no reference to their agreement regarding patient referral allocation; instead, the contracts falsely stated that they "do[] not operate in conjunction with … any other arrangement or agreement between Novartis and [the pharmacy]." *See, e.g.*, PX-4023.

73. Further, when the FDA inquired about operation of EPASS in spring 2009, the FDA the Exjade business team hid from the FDA how the EPASS SPs were implementing their "high-touch nurse programs" for Exjade. Specifically, Novartis concealed the fact that the nurses at those pharmacies were being directed to tell patients that not taking Exjade could cause infertility and organ damages. (Testimony of W. Hinshaw)

74. The Exjade business team also was aware of the problematic nature of the arrangement with the EPASS SPs because, even after the FDA required the addition of the "black box warning" to the Exjade label in January 2010, Novartis took no steps to determine

whether the pharmacies were advising patients consistent with the label. For example, the 2010 label change specified that Exjade was contra-indicated for high-risk MDS patients, and Novartis knew that up to 40% of MDS patients using Exjade were classified as "high-risk." Yet, Novartis made no effort to ensure that the EPASS SPs did not recommend that those patients continue to order Exjade refills.

75. Finally, in September 2010, Novartis executed a Corporate Integrity Agreement (the "CIA") that, among other things, required it to ensure that all promotional and product related functions were conducted in accordance with applicable laws, regulations, and company policies. The Exjade business team avoided implementing the CIA's requirements, such as requiring review of how pharmacies discussed Novartis drugs with patients pursuant to performance-based contracts, to the EPASS SPs because they understood that implementing such requirements would expose the wrongful and illegal nature of the Pay for Performance scheme. *See, e.g.*, PX-361.

2. Novartis Violated the AKS by Giving Kickbacks to Specialty Pharmacies in Return for Recommending Patients Be Switched From Competitor Drugs to Myfortic

76. Novartis manufactures and markets Myfortic, a delayed-release mycophenolic acid tablet that acts as a long-term immunosuppressant used to prevent organ rejection by solid organ transplant recipients. (Stipulation)

77. During the times relevant to this trial, Myfortic's main competitors were CellCept, a brand-name drug marketed by Roche, and, since mid-2009, generic mycophenolate ("generic CellCept" or "generic MMF"). (Stipulation)

78. Novartis knew that Medicare Part B and Medicaid were key sources of coverage funding for Myfortic dispensed by specialty pharmacies, including by Kilgore's, Bryant's, Baylor, Twenty-Ten, and Transcript. (Testimony of, *inter alia*, M. Sachs)

79. When Novartis introduced Myfortic in 2004, CellCept had already been on the market for close to a decade. Thus, one of Novartis's main marketing strategy for Myfortic was to have transplant centers or private practice nephrologists ("PPNs") switch or "convert" patients who were already using CellCept to Myfortic.

80. In furtherance of that marketing strategy, sales and account managers at Novartis's transplant franchise worked to identify specialty pharmacies that could influence whether transplant centers or PPNs used Myfortic or CellCept. When it identified pharmacies that had influence over the choice of Myfortic vs. CellCept, Novartis offered those pharmacies "performance rebate" contracts in return for their unwritten agreements to recommend Myfortic over CellCept or generic MMF.[3] The pharmacies with which Novartis had such kickback relationships submitted thousands of Myfortic claims to Medicare and Medicaid in connection with the kickback arrangements. *See infra* ¶ 123.

81. Novartis concealed the true nature of the kickback arrangements it had with specialty pharmacies in relation to Myfortic because it knew those arrangements were unlawful and improper. Novartis knew this because its own ethics and compliance polices showed how such relationships violated the AKS and because its own internal guidance warned against having undisclosed understanding or agreement with pharmacies. *See*, *e.g.*, PX-3946.

82. To orchestrate this kickback scheme, Novartis executives and managers also avoided implementing the requirements of the 2010 CIA's requirements and made false certifications under the CIA. *See*, *e.g.*, PX-361; PX-2156.

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[3] As noted above, *see supra* n. 2, Novartis bears the burden of proof as to any of its affirmative defenses, including any invocation of an AKS safe harbor; and plaintiffs reserve the right to rebut any such invocation. To the extent that Novartis asserts the "performance rebates" it offered the Myfortic specialty pharmacies to the "discount" safe harbor, such a claim fails in light of, *inter alia*, the failure to disclose the unwritten agreements to recommend in the contracts.

Novartis's Kickback Relationship with Kilgore's Pharmacy

83. In June 2004, a Novartis sales manager at contacted Bob Kilgore, the owner and pharmacist at Kilgore's Pharmacy in Columbia, Missouri, about a discount contract regarding Myfortic. Novartis recognized that Kilgore's was the exclusive pharmacy provider for the Missouri Kidney Program ("MoKP"), a program operated by the University of Missouri that provided certain benefits to transplant patients in Missouri. Novartis knew that Kilgore's Pharmacy and MoKP had agreed to a 50/50 split of any rebate Kilgore's received on drugs used by MoKP patients. (Testimony of R. Kilgore, PX-481)

84. To induce Kilgore's to send recommendations to prescribers to switch patients to Myfortic, Novartis offered Kilgore's a Myfortic "performance rebate" contract. In return, Bob Kilgore promised Novartis that Kilgore's and MoKP would make recommendations to prescribers with patients in the MoKP switch those patients from CellCept to Myfortic. Following execution of that contract, and pursuant to their unwritten agreement with Novartis, Kilgore's and MoKP sent emails, letters, and faxes to prescribers to recommend that they switch their patients from CellCept to Myfortic. (Testimony of R. Kilgore, Testimony of W. Morrissey, PX-485, PX-1846)

85. In 2006, Bob Kilgore re-negotiated his Myfortic contract with Novartis. In return for more favorable market share thresholds for Kilgore's, Bob Kilgore made a "gentleman's agreement" with Novartis – promising to take steps to Myfortic market share to 80% market share by continuing to recommend Myfortic over CellCept. (PX-495)

86. After generic MMF became available in 2009, Myfortic market share began to fall at Kilgore's. In response, Novartis and Kilgore's agreed to a plan to maintain and increase Myfortic market share by having Kilgore's identify patients who had CellCept prescriptions and send faxes to prescribers to recommend switching those patients to Myfortic. Kilgore's also

agreed to provide Novartis with a list of prescribers for Novartis salespeople to "target" to move patients to Myfortic. *See, e.g.,* PX-494.

87. In 2011, as Novartis and Kilgore's were re-negotiating their Myfortic contract, they verbally agreed that Kilgore's would identify transplant physicians with patients who were taking both CellCept/generic MMF and proton pump inhibitors and send faxes to those physicians recommending that they switch their patients to Myfortic. (Testimony of L. Thompson)

88. None of the contracts that Novartis and Kilgore's executed pertaining to Myfortic disclosed their agreement for how the parties would work together to recommend that physicians switch their patients from CellCept/generic MMF to Myfortic.

Novartis's Kickback Relationship with Bryant's Pharmacy

89. In October 2004, transplant sales managers at Novartis contacted Steve Bryant, the owner and pharmacist at Bryant's Pharmacy in Batesville, Arkansas. Novartis recognized that Bryant's was in a position to influence the choice of Myfortic vs. CellCept for patients of the transplant center at Baptist Medical Center in Little Rock, AR and of the PPNs in that area. To induce Bryant's Pharmacy to recommend the use of Myfortic over CellCept, Novartis offered Bryant's a "performance rebate" contract, with the unwritten understanding that Bryant's would recommend Myfortic to prescribers. (Testimony of S. Bryant)

90. In February 2006, the Myfortic "performance rebate" contract for Bryant's Pharmacy was due to terminate or be renewed. To obtain a renewal of that contract, Steven Bryant, the owner of Bryant's Pharmacy, told Novartis that he would work to actively switch patients to Myfortic from CellCept by sending faxes to PPNs recommending such switches. (Testimony of, *inter alia,* S. Bryant and M. Stillwell)

91. In early 2009, Novartis agreed to increase the amount that Bryant's Pharmacy could earn under its Myfortic contract in return for Steven Bryant's efforts to maintain a high market share for Myfortic by recommending that patients remain on Myfortic even after introduction of generic MMF. (Testimony of, *inter alia*, M. Stillwell)

92. In October 2009, after generic MMF became available, Steve Bryant told Novartis that he would continue to recommend the use of Myfortic for existing patients if Novartis would amend Bryant's Pharmacy's "performance rebate" contract by increasing the "rebate" percentage while reducing the "performance" threshold. Bryant also told Novartis that, without an amended contract, he would recommend switching patients to generic MMF. In response to that demand, Novartis retroactively amended the Myfortic "performance rebate" contract for Bryant's Pharmacy in December 2009. *Id.*

93. None of the "performance rebate" contracts between Novartis and Bryant's Pharmacy disclosed their agreements concerning switching patients to Myfortic or keeping patients on Myfortic.

Novartis's Kickback Relationship with Baylor Pharmacy

94. Baylor Hospital in Dallas, Texas, has inpatient and outpatient pharmacy that services approximately transplant patients who received transplants at Baylor Hospital. Through 2009, Baylor Hospital had only CellCept on its formulary for kidney transplants. (Testimony of G. Klintmalm)

95. In September 2009, Novartis offered Baylor a discount term sheet contingent on maintaining a certain market share of Myfortic. The head of Baylor's inpatient pharmacy, John Foster, requested a better Myfortic discount and requested that the same terms be extended to the outpatient pharmacy. *See, e.g.*, PX-1402

96. In October 2009, Foster requested to renew the term sheet and Novartis declined. In response, Foster threatened to "bring on the generic CellCept." *See, e.g.*, PX-4823.

97. It was not until February, 2010 that Novartis and Baylor entered into a rebate contract regarding Myfortic. That contract, which contained a 10% discount for the outpatient pharmacy on all Myfortic sales was contingent on a promise by the pharmacy that it would convert all 200 CellCept patients to Myfortic by the end of May 2010. *See, e.g.*, PX-2637, PX-4824.

98. The February 2010 Letter of Commitment memorializing the myfortic discount was silent as to the agreement by Baylor's outpatient pharmacy to convert all patients to Myfortic.

Novartis's Kickback Relationship with Transcript Pharmacy

99. In April 2005, Novartis and Transcript Pharmacy, a specialty pharmacy in Flowood, Mississippi, amended their existing rebate contract to provide a "performance benefit" for Myfortic. In connection with negotiating contract amendment, Novartis asked Transcript to contact transplant centers to recommend the use of Myfortic over CellCept. (Testimony of C. Osbon)

100. In August 2005 and continuing into 2006, Novartis continued to ask Transcript to increase Myfortic market share to pursue "opportunities for conversion" of patients from CellCept to Myfortic. In July 2007, however, Novartis terminated Transcript's Myfortic "rebate" contract because Transcript "had not met the market share objectives on Myfortic." (Testimony of C. Osbon)

101. In 2009 and 2010, Transcript asked Novartis for a Myfortic "rebate" contract. On July 1, 2011, Transcript advised Novartis by email that, unless Novartis offered a rebate to

Transcript for Myfortic, the pharmacy would recommend to the three transplant centers it served to switch their patients from Myfortic to generic MMF. (PX-1960)

102. A Novartis account manager visited Transcript on July 7, 2011. During that meeting, a co-owner of the Transcript told Novartis that, if offered a rebate contract, he would "create a letter to providers [*i.e.*, physicians] … with a recommendation of moving those patients to Myfortic [from CellCept or generic MMF]." The Transcript co-owner "also reiterated" that, "if [Novartis] can not contract with him," "his intention [was to] convert[] patients from Myfortic to generic mmf." (PX-1960)

103. In response to those proposals, Novartis agreed on July 15, 2011, to give a Myfortic "performance rebate" contract to Transcript. Transcript, in turn, sent out faxes to physicians in late July 2011, recommending that they switch patients from CellCept or generic MMF.

104. The contract that Novartis and Transcript executed in 2011 did not disclose their understanding concerning Transcript's recommendations to switch patients to Myfortic.

Novartis's Kickback Relationship with Twenty-Ten Pharmacy

105. Twenty-Ten Pharmacy is a specialty pharmacy in Los Angeles, California. Starting in 2004, Twenty-Ten had a series of Myfortic contracts with Novartis. In the fall of 2009, Louis Wong, the owner of Twenty-Ten, told Novartis that the pharmacy was having cash flow problems and that he was willing to convert over $6 million of CellCept business to Myfortic. *See, e.g.*, PX-2454, PX-1411, and testimony of M. Sachs.

106. Starting in early 2010, Novartis personnel began to formulate a "super" or "balloon" rebate that would reward Twenty-Ten for agreeing to convert more patients to Myfortic. In March 2010, and in return for Novartis's offer of rebates, Twenty-Ten helped Novartis contact transplant centers to recommend switching patients to Myfortic — leading

Novartis to view Louis Wong as an "amazing advocate for Myfortic." *See , e.g.*, PX-2194 and testimony of K. Antley and M. Sachs.

107. In January 2011, a Novartis sales representative asked Louis Wong whether, in return for a 5% "super rebate," he would be willing to recommend and carry out a large-scale "conversion" of CellCept and generic MMF patients to Myfortic. Wong told Novartis that 5% was enough for him. Throughout early 2011, Novartis and Twenty-Ten also discussed specific steps that Twenty-Ten would take to effectuate the conversion scheme. Based on that commitment from Twenty-Ten, Novartis offered a contract to Twenty-Ten under which Novartis would pay Twenty-Ten up to $950,000 in "rebates" for achieving $5,000,000 in Myfortic sales. *See, e.g.,* PX-1800 and testimony of K. Antley and M. Sachs.

108. Novartis and Twenty-Ten signed a Myfortic "performance rebate" contract in July 2011. But that contract contained no reference to any understanding or agreement between Novartis and Louis Wong concerning the conversion scheme that Wong had agreed to carry out for Novartis. *See, e.g.*, PX-2142.

3. Medicare and Medicaid Reimbursements for Exjade and Myfortic Were Conditioned on Compliance with the Anti-Kickback Statute

The AKS and Comparable State Laws and Regulations Applied to Medicare and Medicaid Claims for Exjade and Myfortic

109. Medicare is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. As relevant to this trial, Part B of the Medicare Program provides supplemental benefits to participants to cover, among other things, physician services and prescription drugs. Part D of the Medicare Program provides prescription drug benefits for Medicare beneficiaries. (Stipulation)

110. Medicaid is a joint federal-state program that provides health care benefits for low-income or disabled families or individuals and certain other groups. (Stipulation)

111. At all times relevant to this trial, including from November 2005 to December 2012, Medicare Part D and Medicaid reimbursed claims submitted by Accredo, BioScrip, and US Bioservices for the Exjade shipments they dispensed. At all times relevant to this trial, including October 2004 to December 2013, Medicare Part B and Medicaid reimbursed claims submitted by specialty pharmacies, including but not limited to Kilgore's Medical Pharmacy, Baylor out-patient pharmacy, Bryant's Pharmacy, Transcript Pharmacy, and Twenty-Ten Pharmacy, for the Myfortic shipments they dispensed. (Testimony of CMS and Medicaid witnesses, *e.g.*, Marc Hartstein)

112. At all times relevant to this trial, products and services, including Exjade and Myfortic, covered by Medicare and Medicaid were subject to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"). The AKS made it illegal to (*i*) "knowingly and willfully solicit[] or receive[] any remuneration in return" for either "referring an individual … for the furnishing ... of any item or service" or "purchasing, leasing, ordering, or arranging for or recommending" the purchase or order of "any good … or item" covered by Medicare or Medicaid; and (*ii*) "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing … or ordering any good . . . or item" covered by Medicare or Medicaid. *Id*.

113. In addition, at the times relevant to this trial, States also had promulgated their own statutes or regulations against kickback relationships in connection with the provision of any goods or services covered by Medicaid. (Testimony of S. Rosenstein)

Specialty Pharmacies Were Required to Comply with the AKS as a Condition of Obtaining Payments from Medicare Part B and Part D

114. During the relevant times, to be eligible for payment under Medicare Part B, pharmacies must certify that, in submitting a claim to payment from Part B, they had complied with, inter alia, the AKS. *See*, *e.g.*, PX-3300 (Kilgore's CMS Form-855S); PX-3295, 3299 (Bryant's CMS Forms-855S).

115. With regard to Part D, the Centers for Medicare and Medicaid Services ("CMS") contracted with Part D plan sponsors to administer prescription drug plans and provided funds to plan sponsors from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a). CMS provided Part D funding to Part D plan sponsors and, in turn, pharmacies conditioned on the plan sponsors' and pharmacies' compliance with all applicable federal laws, regulations, and CMS instructions, including the False Claims Act and Anti-Kickback Statute. *See* 42 C.F.R. §§ 423.505(h)(1), (i)(4)(v).

116. During all relevant times, Accredo, BioScrip, and US Bioservices had subcontracts with Part D plan sponsors.[4] All claims submitted by those pharmacies for Exjade dispensed to Medicare Part D beneficiaries were pursuant to those subcontracts. Each of these subcontracts contained the language required by 42 C.F.R. § 423.505(i)(4)(iv), *i.e.*, that the pharmacies would comply with all applicable federal laws, regulations, and CMS instructions. The contracts between CMS and the Part D plan sponsors with which Accredo, BioScrip, and US

[4] Part D plan sponsors were regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D plan sponsors, in turn, entered into subcontracts with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans. When a pharmacy, such as Accredo, dispensed a drug to a Medicare Part D beneficiary, the pharmacy submitted a claim electronically to the beneficiary's Part D plan sponsor (either directly or through a pharmacy benefit manager, or "PBM"), and the Part D plan sponsor (directly or through the PBM) reimbursed the pharmacy for the portion of the drug cost not paid by the beneficiary if and only if the pharmacy was under a Part D subcontract with the plan sponsor.

Bioservices contracted similarly had provisions concerning AKS compliance required by 42 C.F.R. § 423.505(h)(1).

117. During all relevant times, Part D plan sponsors submitted to CMS electronic notifications of each drug dispensing event, called a Prescription Drug Event ("PDE"), which contains data regarding the prescription claim. Each PDE documented the final adjudication of the claim submitted by a pharmacy. Submitting PDE claims data to CMS was a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322. In submitting the PDE claims data, Part D Plan sponsors and pharmacies certified to the "accuracy, completeness, and truthfulness of the [claims] data" they generate. 42 C.F.R. § 423.505(k). Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" was a condition of payment under the Medicare Part D program.

118. Under the AKS, all Medicare claims submitted on or after March 23, 2010 and in violation of the AKS are impliedly false and ineligible for payment. 42 U.S.C. § 1320a-7b(g).

Specialty Pharmacies Also Were Required to Comply with the AKS as a Condition of Obtaining Payments from Medicaid

119. The States operate Medicaid programs under federal and state laws and regulations. Claims paid by the States' Medicaid programs to Medicaid providers effectively use both federal and state funds. Medicaid is a federal health care program to which the AKS applies.

120. Providers participating in the Medicaid program are required to sign various agreements or certifications that are submitted to state Medicaid programs. The relevant Exjade and Myfortic specialty pharmacies expressly or impliedly certified as a condition of payment that they would comply with applicable federal and state laws or regulations, including the AKS and similar state prohibitions on kickbacks. These certifications rendered the claims submitted by

the SPs in connection with the kickback scheme false. In addition, the AKS renders claims submitted on or after March 23, 2010 in violation of the AKS impliedly false.

121. Novartis also breached various state common law and other statutory claims, including, but not limited to, Washington's RCW 74.09.210, common law fraud, conspiracy, tortious interference with a business expectation.

4. As Part of the Exjade and Myfortic Kickback Schemes, Novartis Is Liable for False Claims Submitted to Medicare and Medicaid in Violation of the FCA

122. None of the claims submitted by the EPASS SPs to Medicare and Medicaid in connection with the Exjade kickback arrangements with Novartis was eligible for payment.

123. In furtherance of the Exjade kickback scheme, the EPASS SPs submitted 60,894 claims to Medicare Part D and 71,356 claims to Medicaid. Each of those claims was false for purposes of the False Claims Act, 31 U.S.C. § 3729 *et seq*. (the "FCA").

124. Through EPASS, Novartis collected dispensing data and knew that the EPASS SPs submitted those claims to Medicare and Medicaid. In addition, Novartis structured its "rebate" arrangement with the pharmacies such that Novartis offered a "rebate" for each of those false Exjade claims.

125. Accordingly, Novartis knowingly caused the submission of each of those false claims. Novartis also knowingly conspired with the EPASS SPs to make each of those false claims.

126. Under the FCA, Novartis is liable for treble damages and penalties – up to $11,000 per claim – for those false claims. *See* 31 U.S.C. § 3729.

127. None of the claims submitted by Kilgore's, Baylor, Bryant's, Transcript, or Twenty-Ten to Medicare and Medicaid in connection with the Exjade kickback arrangements with Novartis was eligible for payment.

128. In furtherance of the Myfortic kickback scheme, those five specialty pharmacies submitted 32,255 claims to Medicare Part B and 5,692 claims to Medicaid. Each of those claims was false for purposes of the FCA.

129. Novartis structured its purported "performance rebate" arrangement with the five specialty pharmacies such that Novartis offered a "rebate" for each of those false claims.

130. Novartis knowingly caused the submission of each of those false claims. Novartis also knowingly conspired with the five specialty pharmacies to make each of those false claims and.

131. Novartis, accordingly, is liable under the FCA for treble damages and penalties – up to $11,000 per claim – for those false Myfortic claims. *See* 31 U.S.C. § 3729.

B. DEFENDANT'S CONTENTIONS

1. EXJADE

Parties

1. Novartis's business involves researching, developing, manufacturing, distributing and selling drugs in many therapeutic areas, including Cardiovascular and Metabolic, Oncology, Neuroscience and Ophthalmics, Respiratory and Immunology and Infectious Diseases. (Boehm Testimony.)

2. Novartis's products are essential to the health and well-being of people worldwide. (Boehm Testimony.)

3. Drug development is inherently uncertain and typically requires significant investment of time and resources. (Boehm Testimony.)

4. Relator David M. Kester is a former account manager for Novartis's cystic fibrosis medicine TOBI and resigned from Novartis on April 19, 2013. (Kester Testimony; DXE-0178; DXE-0183.)

5. Relator never worked in the Oncology division or Transplant division of Novartis. Relator never worked on the Exjade or Myfortic brands and never had any responsibilities with respect to Exjade or Myfortic. (Kester Testimony.)

Specialty Pharmacies ("SPs")

6. SPs dispense specialty medications, i.e., drugs that may be particularly costly or require special handling, administration or monitoring, and that may be used to treat chronic, complex conditions. SPs, together with doctors, are part of the network of health care providers that helps patients with serious diseases manage the complicated drug regimens prescribed by their doctors. (Fein, Sleath Testimony.)

7. SPs provide services to a patient that a regular pharmacy typically does not. For example, SPs provide education services for patients; insurance reimbursement and benefit assistance; drug administration counseling; and information to Health Care Providers ("HCPs") regarding patients' adverse reactions to certain drugs and possible drug-drug interactions. SPs also ensure that there is an adequate stock of medicines to supply patients who need them, especially where there is a small patient population. In addition, SPs provide data to pharmaceutical companies, such as adverse events reports and discontinuation metrics. (Fein, Sleath Testimony.)

8. SPs usually serve patients who live throughout the country. Most of those patients cannot pick up their prescriptions, and the drugs are shipped to them. Although they are not geographically close to their patients, SPs can communicate with patients via phone. (Fein, Sleath Testimony.)

9. SPs help patients adhere to the prescription regimen ordered by their doctors by providing refill reminders and counseling, including counseling on appropriate side effect

management, all of which improve patient outcomes. SPs cannot dispense Exjade or Exjade refills to patients without active prescriptions from the patients' doctors and authorization from the patients to ship the medication. (Fein, Sleath Testimony.)

10. SPs are independent businesses. SPs hire and train their own staffs, which include pharmacists with PharmDs (a doctorate level degree), clinical pharmacists, nurses, medical assistants, customer service representatives, patient care coordinators and business management personnel. SPs have clinical expertise and develop their own policies, business structures, goals and day-to-day activities. (Fein Testimony.)

11. SPs are subject to guidelines and regulations applicable to pharmacists and nurses. SPs and the nurses they employ must be licensed by the states in which they operate. As licensed pharmacies and nurses, they are required to comply with all industry-specific laws and regulations developed by the Boards of Pharmacy in those states. They are not, however, subject to oversight by the FDA's Office of Prescription Drug Promotion (formerly the Division of Drug Marketing, Advertising and Communications ("DDMAC")) because they are not pharmaceuticals manufacturers or marketing agents of manufacturers. It is not industry practice for pharmaceutical companies to submit materials created by third-party SPs to DDMAC for review. (Sleath Testimony.)

12. Novartis contracted with SPs for their independent professional knowledge, expertise and abilities to advise and help patients. (Boehm, Chee, Jolley, Mignogna, Murray Testimony; DXE-0001.)

13. SPs consider their clinical strategies and business operations proprietary. Novartis did not control the SPs' business or clinical decisions, day-to-day activities or interactions with doctors or patients. (Chee, Jolley, Mignogna, Murray, Fein Testimony.)

Exjade Background

14. The FDA approved Exjade, a Novartis product, in 2005 along with its label indication, and, as with all approved drugs, the FDA continues to monitor Exjade's efficacy and safety. Exjade is safe, effective and necessary for patients suffering from transfusional iron overload. (Boehm, Neufeld Testimony.)

15. Once a drug is FDA approved, it is not uncommon for the approved product label to be updated to reflect new clinical data. (Neufeld, Sleath Testimony.)

16. Exjade treats transfusional iron overload by removing excess iron from the body. Patients who receive blood transfusions also receive with each transfusion excess iron that the human body has no active mechanism to excrete. The health consequences of iron overload are serious and can be life-threatening. (Neufeld Testimony.)

17. Exjade is most often prescribed to patients with one of the following underlying diseases: Sickle Cell Disease ("SCD"), Myelodysplastic Syndrome ("MDS") and Thalassemia. (Neufeld Testimony.)

18. SCD is a group of disorders in which a mutation or change in the beta globin gene leads to damage of the red blood cells. The damage causes breakdown of the cells in the blood circulation or "hemolysis", which leads directly to anemia. People with this disorder have abnormally shaped red blood cells which can look like sickles or have spikey, rigid projections that obstruct circulation and can cause damage to internal organs. Some forms of SCD require that patients receive ongoing blood transfusions. (Neufeld Testimony.)

19. MDS is a group of diverse bone marrow disorders, affecting the elderly as well as younger patients, in which the bone marrow does not produce enough healthy blood cells. MDS patients may require blood transfusions, which can lead to iron overload. (Neufeld Testimony.)

20. Thalassemia is a blood disorder in which the globin portion of hemoglobin, the red blood cell protein, is defective. Without regular transfusions, the disorder causes severe debility or death in the first decade of life. Transfusions are administered on nearly a monthly basis for thalassemia patients between the first few months of life and age three or four. (Neufeld Testimony.)

21. Exjade is indicated for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older and in patients 10 years of age and older with non-transfusion-dependent thalassemia syndromes and liver iron concentration of at least 5 mg Fe per gram of dry weight and serum ferritin greater than 300 mcg/L. (DXE-0751.)

22. With multiple blood transfusions, excess iron may accumulate in the heart, liver, lungs, brain, bone marrow and endocrine organs putting patients at risk for a number of conditions. Many of these are not reversible and may be life-threatening, including heart failure, cirrhosis and fibrosis of the liver, gallbladder disorders, diabetes, arthritis, depression, impotence, infertility and cancer. Exjade can reduce liver iron concentration and serum ferritin levels. (Neufeld Testimony.)

23. Because removing excess iron from the blood—a process known as "chelation"—takes time, Exjade needs to be taken regularly, over a period of months or years, as prescribed by a doctor. Exjade therapy requires close patient monitoring, including laboratory tests of renal and hepatic function, monthly serum ferritin, protinuria, serum creatinine and/or creatinine monitoring, and regular blood count and glucose level monitoring. (Neufeld Testimony; DXE-0751.)

24. Exjade is taken orally by dissolving Exjade tablets in water, orange juice or apple juice. (DXE-0751.)

25. Taking Exjade can result in side effects, including mild side effects such as gastrointestinal ("GI") issues and skin rashes, but physicians normally choose to continue therapy through these short-term side effects, which typically resolve on their own or with the help of over-the-counter medications or other side effect management techniques. When patients suffer minor side effects from taking Exjade, those side effects should generally be managed because discontinuation of Exjade results in worse, serious and sometimes fatal health outcomes. (Neufeld, Ness Testimony.)

26. Taking Exjade can also result in rare but serious side effects, such as renal and hepatic toxicity and gastrointestinal bleeding. Patients who experience serious side effects may be instructed by their doctors to stop taking Exjade temporarily or permanently. (Neufeld Testimony.)

27. Before Novartis developed Exjade, no other pharmaceutical company had developed an iron chelator to be taken orally. (Boehm, Jolley, Neufeld Testimony.)

28. Exjade improved the quality of life for patients who were dependent on Desferal. Desferal (deferoxamine mesylate USP), which is also a Novartis product, was the predecessor FDA-approved drug to treat iron overload. Desferal is administered subcutaneously via injection in the abdomen. The injections need to be given daily for 8 to 10 hour periods, meaning that patients on Desferal are attached to an injection pump for close to half the day. The therapy is both painful and creates significant quality of life issues; these features caused many patients who needed to be on an iron chelator to be noncompliant with their Desferal therapy, resulting in severe organ damage and, in some cases, death. (Boehm, Jolley, Mignogna, Neufeld, Padron Testimony.)

29. In an effort to address the issues associated with administering Desferal, Novartis spent years and millions of dollars researching and developing Exjade, and in the process, improved upon its own predecessor product. (Boehm, Jolley, Mignogna Testimony.)

30. Despite Exjade's significant advancement over Desferal, some patients still have trouble adhering to their therapy. Exjade has an unpleasant taste and the medication can take on a sludge-like consistency when mixed with liquid. There can also be mild but unpleasant side effects, particularly at the start of Exjade therapy. (Boehm, Jolley, Mignogna, Neufeld Testimony.)

31. Patients also sometimes have trouble adhering to their Exjade therapy because iron overload is asymptomatic, meaning that iron overload does not—until it is very advanced—cause pain or other symptoms, making it hard for patients to understand why they are taking medication in the first place or to feel any tangible benefits from their Exjade. (Boehm, Jolley, Mignogna, Neufeld Testimony.)

32. After Exjade was approved by the FDA, Novartis spent many additional years and millions of dollars developing a new formulation with the same active ingredient as Exjade, a drug called Jadenu (deferasirox), which is an oral tablet and even easier than Exjade to administer. Jadenu, a once-daily iron chelator that can be swallowed whole, was approved by the FDA in March 2015. (Boehm, Jolley, Mignogna Testimony.)

EPASS

33. When Exjade was launched, Novartis chose to use a limited distribution system, rather than an open system, because Novartis recognized that Exjade patients, who suffer from serious underlying diseases, would benefit from the types of comprehensive patient services that a limited group of SPs could provide. Novartis also recognized that due to the small population

of patients likely to need Exjade compared with the large number of retail pharmacies in the U.S., it was not practical to expect retail pharmacies to stock Exjade—or to become experts in the features of the drug—when they might have only one or two Exjade patients a year. These concerns led to the creation of the EPASS system, which was designed to provide improved patient care and support. (Boehm, Chee, Jolley, Mignogna, Fein Testimony; DXE-38; DXE-0263.)

34. EPASS allowed the SPs to assist patients with every aspect of their Exjade therapy to make it as easy as possible for patients to manage their complicated drug regimens prescribed by their doctors. (Boehm, Chee, Jolley, Mignogna Testimony.)

35. Closed and limited distribution networks were a developing concept when EPASS was created. Due in part to the enormous improvement in patient care resulting from them, limited and closed distribution networks are now more common throughout the SP industry. (Fein Testimony.)

36. Novartis selected SPs for the EPASS network through a Request for Proposal ("RFP") process. As part of that process, SPs were asked to submit materials setting forth their qualifications and experience in all aspects of the patient care process. At the end of the process, Novartis selected three SPs to participate in EPASS. Each of the SPs specialized in a different segment of the market, providing the widest choice possible to patients, HCPs and payors, within the context of a limited distribution system. Novartis chose a small SP (BioScrip), a medium-sized SP (US Bioservices) and a large SP (Accredo) to assess how each type of SP performed in terms of patient care and support. (Boehm, Jolley, Mignogna Testimony; DXE-0001.)

Contractual Agreements Between Novartis and EPASS SPs

37. Novartis entered into contracts with each of the three EPASS SPs in 2005 and 2010 for the distribution of Exjade. Those contracts state that SPs shall fill and dispense pharmaceutical products to each patient "in accordance with the patient's valid prescription". The SPs warranted that they specialized in servicing the needs of patients who require chronic case management and/or complex pharmaceutical care. (DXE-0519; DXE-0529; DXE-0491; DXE-0505; DXE-270; DXE-269.)

38. Under the contracts, the SPs agreed to provide various categories of patient services and to report certain data to Novartis. The SPs agreed to maintain a toll-free telephone service support line for patients, physicians and payors and to staff the support line with a commercially reasonable number of qualified persons able to promptly and accurately answer questions and resolve issues with patients, physicians and payors related to Exjade, Exjade interactions, adverse event reporting, dispensing and reimbursement, all in a manner consistent with any applicable law, rules and regulations governing the practice of pharmacy and mail order pharmacy services. (DXE-0519; DXE-0529; DXE-0491; DXE-0505; DXE-270; DXE-269.)

39. Each of Novartis's Exjade contracts with the EPASS SPs stated that the parties would comply with all federal, state and local laws, rules and regulations in connection with their performance under the contracts, which was understood to include the AKS and FCA, and to fulfill all of their responsibilities in accordance with generally accepted industry practice. The SPs warranted that they would provide information regarding Exjade to patients, healthcare providers and physicians in accordance with applicable laws, rules and regulations, including, but not limited to, enclosing a full package insert for Exjade with every shipment of Exjade.

(Goldfarb Testimony; DXE-0365; DXE-0519; DXE-0529; DXE-0491; DXE-0505; DXE-270; DXE-269.)

40. Novartis reserved the right to terminate its contracts with the SPs without cause as long as it provided the SPs with written notice. (DXE-0519; DXE-0529; DXE-0491; DXE-0505; DXE-270; DXE-269.)

41. The 2005 contracts provided for discounts to be paid on a quarterly basis to the SPs in connection with their dispenses of Exjade to patients. The discount amounts were different for each SP and were the result of individual negotiations between Novartis and each SP. Accredo, for example, as the largest SP with the most negotiating power, received a $110 discount, while BioScrip as the smallest SP received a $13 discount. (DXE-0519; DXE-0529; DXE-0491.)

42. Since the time Exjade was launched, Novartis's medical personnel have continuously provided regular clinical updates to the pharmacies dispensing Exjade, including but not limited to disease information, label changes, ongoing clinical trials and relevant publications. (Chee, Mymo, Nelson Testimony; DXE-0237.)

43. The EPASS SPs also provided their own in-house trainings to employees. Novartis expected the SPs to have properly qualified and trained personnel, but was not itself involved in the in-house training conducted by the SPs. (Chee, Mignogna, Mymo Testimony; DXE-0196.)

SPs' Performance Under the EPASS Contracts

44. In early 2007, Novartis became aware that BioScrip was not meeting its contractual obligations with respect to patient outreach and support, resulting in insufficient care and numerous patients not taking Exjade as prescribed by their doctors. (DXE-0619; DXE-

0621.) BioScrip's internal evaluation of its Exjade program confirmed that its business decisions regarding the form and timing of calls to patients and an understaffed Exjade team were preventing the pharmacy from providing adequate patient services. (Jolley, Mignogna, Murray Testimony; DXE-0099; DXE-0098.)

45. Novartis was concerned that BioScrip patients were not receiving an appropriate level of care. This was especially troubling because of the difficulty Exjade patients had in adhering to and receiving their therapy. Consistent with industry practice, adherence was measured based on dispenses to patients of previously-prescribed Exjade refills. Novartis considered terminating its relationship with BioScrip, but instead chose to give BioScrip an opportunity to try to improve its level of patient care and support. Accordingly, Novartis met with BioScrip management and requested that the pharmacy address its underperformance. (Murray, Mymo Testimony; DXE-0619; PX-2376; DXE-0621.)

46. BioScrip responded by independently creating and proposing its own performance improvement plan. Part of BioScrip's proposal was to use nurses to call Exjade patients. While BioScrip was contractually obligated to contact patients in order to follow up on Exjade shipments and to schedule refills, something that could be done by customer service representatives ("CSRs"), BioScrip decided to use licensed nurses for those calls so that the nurses could also provide counseling to patients on proper management of side effects and compliance with their Exjade treatment. (Corvese, Murray Testimony; DXE-0621; DXE-0163.)

47. BioScrip had developed and used similar nurse programs for drugs manufactured by companies other than Novartis. (Murray Testimony.)

48. BioScrip implemented its Exjade nurse program, and by late 2007 BioScrip became the highest performing SP in terms of patient support, with the highest percentage of patients adherent to their Exjade therapy across all disease types. (DXE-0653; DXE-0651.)

SP Nurse Programs

49. In 2008, both Accredo and US Bioservices created and implemented improvement programs, which included the use of nurses to call and counsel Exjade patients. (Chee, Jolley, Mignogna Testimony; DXE-0204.)

50. The SP nurses provided advice to patients who had already been prescribed and directed to take Exjade. The substance of the advice and counsel provided by the nurses was proprietary to the SPs, and was created and monitored by them, rather than Novartis. The pharmacies did not instruct nurses to minimize the side effects of Exjade in their interactions with patients and the nurses did not do so. (Chee, Creason, Hernandez, Jolley, Lisby, Mignogna, Mymo Testimony; DXE-0196.)

51. The pharmacies shipped Exjade refills to only those patients who had been prescribed Exjade refills by their doctors. (Engelhardt, Hernandez, Lisby Testimony.)

52. Consistent with industry standard, the SPs had call scripts to be used by their employees when communicating with patients, many of which were developed and approved by pharmacists, including PharmDs, at the SPs. The call scripts specified when an issue should be escalated to a nurse, pharmacist or the patient's doctor, depending on the type of question. In particular, the scripts provided that pharmacy personnel should direct patients to their doctors if patients complained of a serious side effect or a minor side effect that was not improving. Novartis did not draft or provide feedback on the call scripts. (Chee, Engelhardt, Jolley, Mignogna Testimony; DXE-0081.)

53. Novartis never approved or rejected any patient education materials prepared by the SPs. Such materials did not require Novartis's approval and were developed and used by the SPs without Novartis's approval. (Chee, Engelhardt, Mignogna, Nelson Testimony.)

54. Novartis regularly held information sessions for the SPs' nurses, pharmacists and other employees on Exjade and iron overload, including presentations regarding updates to Exjade's label and adverse event reporting. Novartis also distributed educational materials to the pharmacies with important drug information to provide additional information to nurses making patient calls. (Engelhardt, Lisby, Mymo, Nelson Testimony; DXE-0219; DXE-0237; DXE-0112; DXE-0240; DXE-0151.)

55. The SPs also endeavored, as part of their increased adherence efforts, to contact Exjade patients who had inappropriately discontinued their therapy—Exjade patients who had stopped taking Exjade despite their doctors' orders that they should continue with Exjade treatment. The recovery efforts used by the SPs involved contacting physicians and patients to determine the bases for patient discontinuations and to restart patients on Exjade therapy where those patients had discontinued for clinically inappropriate reasons. Often prescribing physicians were not aware that their patients had stopped taking their medications. The pharmacies did not restart patients whose doctors had advised them to stop taking Exjade. (Chee, Garcia, Hernandez, Jessee, Lisby, Mignogna, Murray, Sack, Scott, Williams Testimony; DXE-0445; DXE-0654.)

56. The work that the SPs performed benefited patients. If patients did not adhere to Exjade therapy, their elevated iron levels went untreated. Additionally, restarting Exjade after an unnecessary lapse in therapy sometimes caused patients to experience for a second or third time (or more) the side effects that can occur in the first several days of treatment; continuous therapy

mitigates some of these side effects for patients. (Boehm, Jolley, Mignogna, Neufeld Testimony.)

57. Novartis did not control or monitor the pharmacies' calls to patients. Therefore, even if pharmacy employees were inappropriately counseling patients, as alleged, Novartis was unaware. (Jolley, Murray, Mymo Testimony; DXE-0120; DXE-0160.)

58. In 2011, Novartis met with BioScrip to discuss a decrease in its adherence rates and overall performance in terms of patient care. BioScrip employees acknowledged that the pharmacy was having management and operational difficulties at the time. (Friedman, Smith Testimony; DXE-0601; DXE-0659.)

Performance-Based Rebates

59. To further enhance patient care through greater adherence, Novartis amended the EPASS contracts to include performance incentives. These performance incentives took the form of additional rebates if the pharmacies achieved certain adherence metrics set forth in the amended contracts. In the case of BioScrip, Novartis also increased the base per shipment rebate by $7; Novartis believed the initial rebate was too low in light of the contracted-for services and the rebates paid to the other two SPs. (Chee, Jolley, Mignogna Testimony; DXE-0443.)

60. Performance rebates were first introduced into Novartis's contracts with EPASS SPs in 2008 through amendments. Each of those amendments underwent legal review by Novartis's counsel prior to incorporation in the contracts. Subsequently, amendments to the performance rebate targets and terms in April 2008, July 2008, August 2008, October 2008, January 2009, April 2009, July 2009, October 2009 and January 2010 were reviewed by counsel prior to incorporation in the contracts. (Goldfarb, McGee Testimony; DXE-0534; DXE-0541;

DXE-0535; DXE-0542; DXE-0533; DXE-0540; DXE-0544; DXE-0523; DXE-0557; DXE-0412.)

61. The rebates in the 2008 contract amendments were based on the volume of Exjade shipped to patients by each SP. All the terms and conditions for receiving the discounts and rebates were outlined in the contracts. (Chee Testimony; DXE-0534; DXE-0509; DXE-0492.) Volume-based contractual rebates are common in the pharmaceutical industry. (Fein Testimony.)

62. In June 2010, Novartis entered into new contracts with the SPs that incorporated performance rebates determined by the number of shipments per patient. The 2010 contracts were reviewed and approved by Novartis's in-house counsel before they were implemented. (Goldfarb Testimony; DXE-0505; DXE-0270; DXE-0269; DXE-0325.)

63. In-house counsel for Novartis consulted Joe Metro, an attorney at Reed Smith LLP, to ensure that the performance rebates outlined in the EPASS contracts did not violate the AKS. Mr. Metro advised that the performance rebates in the contracts were protected by AKS safe harbors. (McGee, Metro, Goldfarb Testimony; DXE-0398; DXE-0361; DXE-0283.)

64. Novartis required that in-house counsel review its EPASS contracts (including the proposed performance rebate component) and proposed business plans to ensure they complied with all legal requirements prior to implementation. As part of the review process, in-house counsel were provided with draft contracts and presentations fully detailing the proposed agreement or business plan subject to legal review. (Chee, Jolley, Goldfarb, McGee Testimony; DXE-0346; DXE-0364; DXE-0442; DXE-0298; DXE-0391; DXE-0299.)

65. All Novartis employees, including Novartis attorneys, received regular training on the AKS and FCA and were familiar with their requirements. In-house attorneys also consulted

with outside counsel who had expertise in the relevant area. (Goldfarb, McGee, Metro, Ng, Nelson Testimony.)

Patient Allocation

66. Novartis also changed the way in which it allocated "undesignated" patients among the three pharmacies in order to improve patient care. When a doctor prescribes Exjade, there is an "EPASS form" that the doctor fills out, which is then submitted to the EPASS administrator, a third party called LASH. The form allows LASH to allocate patients based on doctor, payor or patient preference. In approximately half of the EPASS forms received by LASH, there is no preference among the three pharmacies, meaning these patients are unallocated. (Boehm, Jolley, Mignogna Testimony; DXE-0360.)

67. When EPASS first started, the unallocated patients were divided among the three pharmacies evenly in a round-robin fashion (that is, one-third, one-third, one-third). In late 2007, Novartis employees who worked on the Exjade account suggested that the allocation process be changed from an even allocation to one based on adherence. They strongly believed that patient care would be improved if the SP (or SPs) offering the best care treated more Exjade patients. They also hoped the change would incentivize the underperforming SP (or SPs) to improve their patient care. (Chee Testimony; DXE-0642.)

68. Novartis considered this proposal for more than a year, including legal review by in-house and outside counsel. At the end of that review, in January 2009, Novartis implemented adherence-based allocation, with 60% of unallocated patients assigned to BioScrip and 20% going to each of Accredo and US Bioservices. Those allocations were periodically adjusted as the adherence levels achieved by the three SPs changed over time. (Chee, Goldfarb, McGee, Metro Testimony; DXE-0641; DXE-0444.)

69. In April 2008, business personnel consulted with Elizabeth McGee, in-house counsel for Novartis, regarding the proposed plan to allocate new patients to SPs based on adherence. (Chee, McGee Testimony; DXE-0303.)

70. Ms. McGee consulted Mr. Metro on the issue of allocation and initially provided legal advice to the effect that allocation of undesignated patients based on adherence would not be recommended pending her evaluation of additional information regarding the goals of the program and alternative methods of achieving those goals. (McGee, Metro Testimony; DXE-0306.)

71. As is its practice, Novartis followed this legal advice and did not go forward with its plan to reallocate patients in 2008. (Chee Testimony; DXE-0222)

72. By late 2008, after further analysis and discussion, Ms. McGee (with continuing advice from Mr. Metro) approved adherence-based allocation. (Chee, Metro, McGee Testimony; DXE-0299; DXE-0406.)

73. After receiving legal approval, Novartis began to allocate undesignated patients among the SPs in January 2009 based on adherence. In-house counsel advised that Novartis's contracts with the SPs did not need to be amended because the contracts did not mandate a particular allocation. (Chee, McGee Testimony; DXE-0284.) However, the criteria for the allocation program were set forth in writing and provided to the SPs. (DXE-0208; DXE-0200.)

74. Novartis used adherence-based metrics because adherence was considered a fair proxy for successful patient health outcomes. Novartis commissioned studies to measure patient satisfaction in other ways and found that adherence was the best metric for measuring patient care that could be evaluated as frequently or expediently as Novartis required. Adherence was measured based on the amount of Exjade dispensed by the SPs. (Chee, Jolley Testimony.)

75. Adherence is a standard metric used to evaluate performance in the pharmaceutical industry, including by government payors such as Medicare Part D. Government payors evaluate SPs based on adherence. (Fein Testimony.)

76. Indeed, government payors ask BioScrip to show them its adherence rates; they ask BioScrip about its interventions and they ask it to report outcomes to them. (Murray Testimony.)

77. Government payors require BioScrip to guarantee that it will make outreach calls to patients to promote adherence because proper patient adherence saves the government money. (Murray Testimony.)

78. The government encourages and uses adherence programs because it recognizes that patients are healthier when they are adherent to the drug therapies prescribed by their doctors. (DXE-0791.)

79. BioScrip reported on its adherence activities in its public financial filings. (DXE-0711; DXE-0712; DXE-0713; DXE-0714; DXE-0715.)

80. Novartis did not ask any SP to suspend its independent professional judgment when counseling Exjade patients. Nor did any SP employees who regularly interacted with Novartis believe that Novartis intended for the SPs to suspend their independent professional judgment. (Chee, Jolley, Mignogna, Murray, Mymo Testimony.)

81. Novartis was not perceived by any SP as attempting to gain influence over the reason or judgment of the pharmacies. (Chee, Deno, Jolley, Mignogna, Murray, Mymo Testimony.)

82. None of the SP personnel who regularly interacted with Novartis believed he/she or Novartis violated any laws or ethical obligations. (Hernandez, Murray, Mymo Testimony.)

83. Actions taken by Novartis with respect to matters alleged in the complaints were taken in accordance with established industry practice. (Fein Testimony.)

84. Neither Novartis nor the SPs ever took any steps to conceal the details of their financial relationship regarding Exjade. (Chee, Jolley Testimony.)

85. When doctors prescribe Exjade, they expect the patients to take it, and they expect health care professionals such as pharmacists and nurses to help the patients comply with the doctors' orders. Doctors regularly meet with their patients, all of whom have serious underlying diseases, and address patients' side effects (to determine, among other things, whether a side effect is caused by Exjade or another of the many drugs these patients take), including by obtaining blood work to monitor developments such as renal and hepatic toxicity levels. (Neufeld Testimony.)

86. Novartis never misled the FDA about Exjade adverse events ("AEs"), side effects or efficacy. As is Novartis's practice, it spent time and resources to respond accurately and fully to any FDA inquiry, investigation and/or request. (Chee, Goldfarb, McGee Testimony.)

87. In its contracts with the EPASS SPs, Novartis required that the SPs report Exjade AEs pursuant to all relevant laws and regulations. Novartis provided trainings to SP employees on how to report AEs properly. (Goldfarb, Luery Testimony; DXE-0519; DXE-0491; DXE-0529; DXE-0501; DXE-0524; DXE-0488; DXE-0245; DXE-0405; DXE-0276.)

88. Novartis never asked, encouraged or intended for an EPASS SP to promote Exjade to any patient; the patients with whom the SPs communicated had already been prescribed Exjade by their doctors. Novartis did not believe the SPs were promoting Exjade. Consequently, Novartis never contemplated, nor believed it was necessary, to seek review of the SPs' scripts and patient education materials. (Chee, Jolley Testimony.)

Novartis's Actions Were Not Unlawful

89. In order to prevail on their claims under 31 U.S.C. §§ 3729(a)(1)(A) & (B) and their state law analogues, Plaintiffs must establish that (1) the SPs made a false or fraudulent claim or statement, (2) Novartis knew that the claim or statement was false or fraudulent, (3) Novartis knowingly caused the false or fraudulent claim or statement to be made to Plaintiffs, (4) the false or fraudulent claim or statement was material to Plaintiffs' decision to pay, and (5) as a result of the false or fraudulent claim or statement, Plaintiffs suffered damages. 31 U.S.C. §§ 3729(a)(1)(A) & (B), 3731(d); *U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 86 (2d Cir. 2012); *U.S. ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 432, 440 (S.D.N.Y. 1999) (McMahon, J.).

90. Plaintiffs allege that the claims or statements submitted by the SPs in connection with reimbursements for Exjade were false or fraudulent because Novartis and the SPs were violating the AKS. To prove that Novartis violated the AKS, Plaintiffs must establish, to the extent an exception or safe harbor does not apply, that Novartis (1) knowingly and willfully (2) offered or paid remuneration (3) to induce the SPs to recommend purchasing or ordering Exjade (4) that would be reimbursed by Plaintiffs' government health care programs. 42 U.S.C. § 1320a-7b(b)(2)(B).

91. To prove that the SPs violated the AKS, Plaintiffs must establish, to the extent an exception or safe harbor does not apply, that the SPs (1) knowingly and willfully (2) solicited or received remuneration (3) in return for recommending purchasing or ordering Exjade (4) that would be reimbursed by Plaintiffs' government health care programs. 42 U.S.C. § 1320a-7b(b)(1)(B).

92. In order to show that Novartis knew that the certifications of compliance with the AKS were false, Plaintiffs must prove that Novartis either actually knew that the certifications of compliance with the AKS were false or acted in deliberate ignorance or reckless disregard of whether the certifications of compliance with the AKS were false. 31 U.S.C. § 3729(b)(1). As part of that burden, Plaintiffs must show that Novartis actually knew that there was a violation of the AKS or acted in deliberate ignorance or reckless disregard of whether there was a violation of the AKS. *See Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

93. Novartis did not violate the AKS or any of its state law counterparts. 42 U.S.C. § 1320a-7b(b)(2)(B).

94. Novartis and the SPs did not act knowingly and willfully under the AKS. Novartis employees did not know or believe that their actions with the SPs were wrong or unlawful. (Chee, Goldfarb, Jolley, McGee Testimony.) SP employees did not know or believe that their actions were wrong or unlawful. (Murray Testimony.) *See, e.g., Mikes*, 274 F.3d at 703; *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996).

95. Novartis employees acted in good faith with respect to all aspects of the EPASS program and believed that they were acting in the best interest of patients. (Chee, Jolley, McGee, Goldfarb Testimony.)

96. Novartis employees sought, in good faith, the advice of attorneys, who vetted and approved all aspects of the EPASS program. The business teams shared all relevant facts with the lawyers, who analyzed the program and proposed changes to the program over time in light of the plain language and meaning of the AKS together with all available guidance and who ultimately approved the program. Novartis employees acted in accordance with the advice they received from counsel. (Chee, Goldfarb, McGee, Metro Testimony.) *See U.S. ex rel. Pogue v.*

Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153, 167 (D.D.C. 2008); Jain, 93 F.3d at 440-41.

97. The adherence-based allocation of Exjade patients was a focus of legal scrutiny, including by both in-house and outside counsel. (Chee, McGee, Metro Testimony; DXE-0303; DXE-0306; DXE-0299; DXE-0406; DXE-0284.) The legal scrutiny and approval foreclose Plaintiffs from showing knowledge or willfulness, especially in the absence of any caselaw or guidance that condemned this type of adherence program and adherence-based allocation as violative of the AKS. *See U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479 (S.D.N.Y. 2006).

98. Moreover, adherence programs are typically favored by payors, including government payors, because they ultimately save the payors money. (Gaier Testimony; DXE-0791.) Government encouragement of adherence programs and common industry practice are further evidence that Novartis employees did not have knowledge that their actions were wrong or unlawful. *See U.S. ex rel. Williams v. Renal Care Grp., Inc*., 696 F.3d 518, 531 (6th Cir. 2012); *U.S. ex rel. Quirk v. Madonna Towers, Inc*., 278 F.3d 765, 768 (8th Cir. 2002); *U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp*., 985 F.2d 1148, 1156-57 (2d Cir. 1993).

99. Novartis was not seeking "to induce" the SPs to recommend to patients that they order Exjade, and the SPs were not seeking to recommend Exjade "in return for" remuneration. *See United States v. LaHue*, 261 F.3d 993, 1003 (10th Cir. 2001); *United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012). The allocation of undesignated Exjade patients based on performance is not a "kickback" within the meaning of the AKS. To the extent that Novartis offered or paid remuneration to SPs, Novartis intended to provide Exjade patients with the best medical care and support, and it never intended to cause SPs to recommend orders of Exjade

because of any influence of that remuneration over the SPs' independent professional judgment (and the SPs, in any event, had no influence over any prescribing decisions). (Chee, Jolley, Mignogna Testimony.)

100. Moreover, the SPs did not perceive that Novartis was attempting to cause them to set aside their professional judgment. (Deno, Murray, Mymo Testimony.) In fact, the SPs did not set aside their professional judgment because of the influence of remuneration offered or paid by Novartis, and Novartis was not aware of any SP setting aside its professional judgment. (Chee, Deno, Jolley, Mignogna, Murray, Mymo Testimony.) Instead, the SPs developed their own proprietary programs based upon best practices in the specialty pharmacy industry and the relevant clinical science. (Chee, Jolley, Mignogna, Murray Testimony; DXE-0621.) Both the SPs and Novartis understood that compliance with Exjade therapy correlates with survival and helps prevent the severe effects of iron overload, and consequently believed it was very important to ensure that patients complied with their doctors' orders. (Boehm, Chee, Hernandez, Jolley, Mignogna, Murray Testimony.)

101. Novartis was not seeking to induce the SPs to "recommend" Exjade as that term is used in the AKS. Novartis knew that the EPASS pharmacies did not prescribe or "recommend" Exjade for purposes of the AKS. Novartis further knew that patients entered the EPASS system only after their doctors prescribed Exjade, including some number of Exjade refills. There is no allegation or even suggestion that anyone—Novartis or the SPs—influenced or sought to influence the doctors' decisions to prescribe Exjade. This means that when the SPs contacted Exjade patients about refilling their Exjade as prescribed, they were merely implementing the doctors' orders; they were not "recommending" anything at all. When they did contact patients, SPs were simply asking the patients if they would like a refill, sometimes combined with

counseling on side effects or education about the importance of remaining adherent to the therapy. Novartis had no knowledge of any recommendations made by any SPs and did not intend to induce any such recommendations. (Chee, Jolley, Mignogna, Ng Testimony.)

102. Moreover, even assuming it is relevant for purposes of determining a violation of the AKS or FCA, the EPASS SPs sufficiently trained their employees, the SPs did not instruct or expect their employees to have improper interactions with patients, and Novartis was unaware of any insufficient training of EPASS SPs' employees or any improper interactions with Exjade patients. (Chee, Jolley, Murray, Mymo, Scott, Tadlock Testimony; DXE-0120; DXE-0160; DXE-0242.)

The Statutory Exception and Regulatory Safe Harbor Apply

103. All rebates and discounts Novartis paid to the Exjade SPs fall squarely within the statutory exception and the regulatory safe harbor of the AKS. 42 U.S.C. § 1320a-7b(b)(3)(A), (E); 42 C.F.R. § 1001.952(h)(2).

104. By its terms, the AKS does not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program". 42 U.S.C. § 1320a-7b(b)(3)(A); *see, e.g., U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003).

105. In addition to this statutory exception for discounts and other price reductions, the AKS does not apply to "any payment practice specified by the Secretary" of Health and Human Services in applicable regulations. 42 U.S.C. § 1320a-7b(b)(3)(E). These regulations provide a safe harbor to entities such as Novartis that sell to buyers. 42 C.F.R. § 1001.952(h)(2)(iii)(B);

see U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc., No. 13CV3779, 2014 WL 6750786, at *7-8 (S.D.N.Y. Dec. 1, 2014) (Cote, J.). Novartis complied with all the requirements of the statutory exception and the regulatory safe harbor. (Chee, McGee, Metro Testimony; DXE-0226; DXE-0127; DXE-0238; DXE-0050; DXE-0270; DXE-0269; DXE-0519; DXE-0529; DXE-0491.) It is Plaintiffs' burden to demonstrate that the discounts and rebates provided by Novartis did not fall under either the statutory exception or the regulatory safe harbor, and they cannot prove either. *See U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc*., No. 13CV3779, 2014 WL 6750786, at *9 (S.D.N.Y. Dec. 1, 2014) (Cote, J.).

106. With respect to Exjade, in the 2005 contracts, Novartis and the SPs included a provision requiring the SPs to report the discounts set forth in the contracts to "appropriate authorities as may be required of them by law". (DXE-0519; DXE-0529; DXE-0491.) The 2010 contracts stated that the "SPP shall reflect the value of discounts and rebates submitted to Federal Healthcare Programs, shall retain invoices and other documentation of discounts provided by Novartis and shall make this documentation available to state and Federal authorities upon request". (DXE-0505; DXE-0270; DXE-0269.)

107. From November 2008 onwards, Novartis and the SPs also included a contractual provision expressing their intent to have the rebates fall under the discount safe harbor and statutory exception. (DXE-0512; DXE-0532; DXE-0494.) They believed their agreements fell under these carve outs, and they did not think they were doing anything wrong or unlawful. (Chee, Metro, Goldfarb Testimony.) Additionally, both Novartis and the SPs had systems established for the review of their contracts that included review by their legal counsel. (Goldfarb, McGee, Murray Testimony.) The approval of legal counsel shows that Novartis did

not intend to do anything wrong or believe that it was doing anything wrong. *See Pogue*, 565 F. Supp. 2d at 167; *Jain*, 93 F.3d at 440-41.

108. Even assuming that Novartis had a reasonable but incorrect interpretation of the statutory exception or regulatory safe harbor with respect to Exjade, such technical failure to comply was not knowing. "[U]nresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant's interpretation of the governing law is reasonable." *U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479, 488 (S.D.N.Y. 2006) (McMahon, J.) (internal quotation marks omitted).

Novartis Did Not Violate the FCA or Any State Analogues or Related State Laws

109. Causes of action under the FCA, any state equivalents or related state laws are predicated on an underlying violation of the AKS, and, without a violation of the AKS, there can be no FCA or other state law cause of action because the certifications of compliance with the AKS were not false. *U.S. ex rel. Kester v. Novartis Pharms. Co*. (*Novartis IV*), 41 F. Supp. 3d 323, 335 (S.D.N.Y. 2014). Moreover, as noted above, with respect to Exjade, Novartis investigated whether its actions were wrong or unlawful by asking internal and external legal counsel, and it therefore did not recklessly disregard, deliberately ignore or actually know that there was a violation of the AKS. *See Pogue*, 565 F. Supp. 2d at 167; *Jain*, 93 F.3d at 440-41.

110. Even assuming a violation of the AKS, no violation of the FCA exists because Plaintiffs cannot prove that any act by Novartis caused claims to be made that would not have been made absent any kickbacks. *See* 42 U.S.C. § 1320a-7b(g); *U.S. ex rel. Chen v. EMSL Analytical, Inc.*, No. 10-7504, 2013 WL 4441509, at *18 (S.D.N.Y. Aug. 16, 2013); *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-1806, 2013 WL 1346022, at *3-4 (E.D.N.Y. Apr. 3, 2013); *U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003).

111. Doctors prescribed Exjade and Exjade refills irrespective of anything Novartis or the EPASS pharmacies said or did. (Engelhardt, Hernandez, Lisby, Neufeld Testimony.) Plaintiffs need to prove that a particular patient ordered a refill that was not consistent with the independent clinical judgment of his or her physician. Plaintiffs cannot establish this because there is no evidence in the record to prove such a situation. *Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1362 (11th Cir. 2011); *UFCW Local 1776 v. Eli Lilly & Co*., 620 F.3d 121, 135 (2d Cir. 2010).

112. To the extent the Government is merely saying that Novartis and/or the SPs convinced patients to order medically necessary refills that they otherwise might not have, that is (1) appropriate adherence to a prescribed course of treatment, (2) consistent with a prescriber's recommendation and (3) good for all parties, including the Government. Plaintiffs cannot prove that Novartis's conduct "result[ed] in" any "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a) or any state equivalents. (Gaier Testimony.)

113. Plaintiffs cannot establish that any particular individual at Novartis with authority to act on behalf of the Company had sufficient knowledge of the alleged kickback scheme to constitute institutional knowledge necessary for an FCA violation. *See U.S. v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010).

114. Novartis acted in "good faith" with respect to all aspects of the EPASS program. *See, e.g., Mikes*, 274 F.3d at 703-04; Jain, 93 F.3d at 440.

115. Plaintiffs cannot prove any conspiracy claims because Plaintiffs are unable to show an underlying actionable claim. Moreover, Plaintiffs cannot prove that Novartis and any other entity had an agreement and specific intent to defraud the government. *See Allison Engine*

Co., Inc. v. U.S. ex rel. Sanders, 553 U.S. 662, 672-73; *U.S. ex rel. Wuestenhoefer v. Jefferson*, No. 4:10-CV-00012, 2015 WL 226026, at *25 (N.D. Miss. Jan. 16, 2015).

116. The States of Maryland, Michigan, New Jersey, Oklahoma and Washington (the "Common Law Fraud States") cannot show that Novartis committed common law fraud (known as intentional misrepresentation in Maryland) because Novartis did not make a material false representation to the Common Law Fraud States; Novartis did not know or recklessly disregard that any such representation was false; Novartis did not make any representation with the intention that it should be acted upon by the Common Law Fraud States; the Common Law Fraud States did not pay claims in reliance upon any such representation and did not sustain injury as a result of reliance upon the statement. *See White v. Kennedy Krieger Inst., Inc*., 110 A.3d 724, 744 (Md. Ct. Spec. App. 2015); *Titan Ins. Co. v. Hyten*, 817 N.W.2d 562, 567 (Mich. 2012); *Banco Popular N. Am. v. Gandi*, 876 A.2d 253, 260 (N.J. 2005); *Bowman v. Presley*, 2009 OK 48, ¶ 13, 212 P.3d 1210, 1217-18; *Elcon Constr., Inc. v. E. Wash. Univ*., 273 P.3d 965, 970 (Wash. 2012).

117. The States of Oklahoma and Washington cannot prove that Novartis committed civil conspiracy because Novartis did not enter into an agreement or combination with any other person to do an unlawful act, or to do a lawful act by unlawful means. Novartis did not pursue an independently unlawful purpose or use independently unlawful means. *Brock v. Thompson*, 1997 OK 127, ¶ 39, 948 P.2d 279, 294; *Bonneville v. Pierce Cty*., 202 P.3d 309, 318 (Wash. Ct. App. 2008).

118. The State of Indiana cannot prove that Novartis committed theft because Novartis did not knowingly or intentionally exert unauthorized control over property of the State of

Indiana with intent to deprive the State of Indiana of any part of its value or use. Ind. Code Ann. § 35-43-4-2 (West 2013) (effective until June 30, 2014).

119. The State of Indiana cannot prove that Novartis committed Medicaid Fraud because Novartis did not knowingly or intentionally obtain payment from the Medicaid program under Ind. Code Ann. § 12-15 by means of a false or misleading written statement or other fraudulent means and because Novartis did not knowingly or intentionally conceal information for the purpose of applying for or receiving unauthorized payments from Indiana's Medicaid program. Ind. Code Ann. §§ 35-43-5-7.1(a)(2), (5) (West 2013) (effective until June 30, 2014). The State of Indiana's claims under Ind. Code Ann. § 35-43-5-7.1(a)(1) should be dismissed because the Indiana Supreme Court has ruled that provision unconstitutional. *Healthscript, Inc. v. Indiana*, 770 N.E.2d 810, 816 (Ind. 2002).

120. The State of Illinois cannot prove Novartis committed Public Assistance Fraud because Novartis did not willfully, by means of a false statement or representation, or by concealment of any material fact or by other fraudulent scheme or device on behalf of itself or others, obtain or attempt to obtain benefits or payments under Illinois's Public Aid Code to which it was not entitled, or in a greater amount than that to which it was entitled. 305 Ill. Comp. Stat. Ann. 5/8A-7(b).

121. The State of Maryland cannot prove that Novartis committed constructive fraud because Novartis did not breach a legal or equitable duty to Maryland in a way that tends to deceive others, to violate public or private confidence, or to injure public interests. Canaj, Inc. v. Baker and Division Phase III, LLC, 893 A.2d 1067, 1095 (Md. 2006). As the Court has already ruled in the context of negligent misrepresentation, "Novartis owed no duty to the State of Maryland". (Mem. & Order ("*Novartis VI*") at 25-26, Sept. 4, 2014, ECF No. 234.)

122. The State of New Jersey cannot prove that Novartis committed conversion because Novartis has not intentionally and wrongfully exercised dominion and control over property owned by the State of New Jersey inconsistent with New Jersey's rights. *LaPlace v. Briere*, 962 A.2d 1139, 1145 (N.J. App. Div. 2009).

123. The State of New York cannot prove that Novartis committed repeated fraudulent acts because Novartis has not engaged in repeated fraudulent or illegal acts or otherwise demonstrated persistent fraud or illegality in the carrying on, conducting or transaction of business. N.Y. Exec. Law § 63(12).

124. The State of New York cannot prove that Novartis committed misappropriation of public property because Novartis has not obtained, received, converted, or disposed of money, funds, credits, or other property, held or owned by the State of New York. N.Y. Exec. Law § 63-c(1).

125. The State of Washington cannot prove that Novartis committed tortious interference because it cannot prove (1) the existence of a valid contractual relationship or business expectancy; (2) that Novartis had knowledge of that relationship; (3) that Novartis intentionally induced or caused BioScrip to breach or terminate that relationship or business expectancy (4) for an improper purpose or using improper means (5) with resulting damage. *Moore v. Commercial Aircraft Interiors, LLC*, 278 P.3d 197, 200 (Wash. Ct. App. 2012).

126. Washington cannot prove that Novartis committed fraudulent practices because Novartis did not (1) obtain or attempt to obtain payments from Washington (2) greater than that to which it was entitled (3) by making a false statement or a misrepresentation to the State of Washington, or by concealing material facts from the State of Washington, or by some other

fraudulent scheme or device; and (4) Novartis did not act knowingly and willfully. Wash. Rev. Code Ann. § 74.09.210(1)(a)-(c) & (2) (West 2015).

127. Damages

128. Plaintiffs cannot establish liability under the FCA or state laws because they cannot prove the essential element of damages. 31 U.S.C. § 3731(d). (Gaier Testimony.)

129. There is no evidence that the United States or state governments sustained damages "because of the act[s] of" Novartis, as required under 31 U.S.C. § 3729(a)(1). Even assuming for purposes of argument that the SPs and Novartis violated the AKS, the United States and state governments would have made the same reimbursement payments absent such violations. (Gaier Testimony.)

130. For any allegedly fraudulent Exjade Medicare or Medicaid claim reimbursement, if those claims would have been submitted and reimbursed even had there been no alleged kickbacks, then there are no damages because the United States and state governments did not pay any money as a result of the allegedly false claim. (Gaier Testimony.)

131. Even if Plaintiffs demonstrate liability, the number of statutory penalties owed would be limited to the number of fraudulent acts committed by Novartis itself. *United States v. Bornstein*, 423 U.S. 303, 313 (1976). If any statutory penalties are awarded, they should be in the lowest amount possible under the FCA or state equivalent statutes for all of the reasons that Novartis argues it should not be found liable under the AKS, FCA and state equivalent statutes. (Gaier Testimony.)

132. Plaintiffs cannot prove that Plaintiffs' injuries were proximately caused by the acts or omissions of Novartis; if injuries exist at all, they were the result of intervening or superseding causes. (Gaier Testimony.)

133. Plaintiffs' claims fail because they have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the complaints. (Gaier Testimony.)

134. To the extent Plaintiffs obtain or obtained recovery in any other proceeding or settlement predicated on the same factual allegations, Plaintiffs cannot obtain a double recovery against Novartis. (Mem. & Order ("*Novartis VI*") at 22, Sept. 4, 2014, ECF No. 234.)

135. Plaintiffs' claims violate Novartis's rights under the Due Process and Ex Post Facto Clauses of the United States Constitution and the Constitutions of the states, insofar as Plaintiffs seek to impose liability retroactively for conduct that was not prohibited when it took place. *Landgraf v. USI Film Products*, 511 U.S. 244, 266 (1994).

136. Plaintiffs' claims fail because they are too remote and speculative to form the basis for relief. *See Clapper v. Amnesty Int'l USA*, 133 S.Ct. 1138, 1160-61 (2013).

2. MYFORTIC

Background

1. Myfortic is a safe and effective medication that prevents organ rejection in patients who have received kidney transplants. (Cooper, Langone Testimony; DXM-0563; DXM-0570; DXM-0576; DXM-0580; DXM-0587; DXM-0591; DXM-0593; DXM-0599; DXM-0603; DXM-0607.)

2. In connection with obtaining marketing approval for Myfortic, Novartis conducted two clinical trials. The first trial demonstrated that Myfortic was as safe and effective as CellCept in de novo (i.e., new) renal transplant patients. The second trial demonstrated that converting a patient from CellCept to Myfortic was safe and effective for maintenance patients (i.e., patients who had already received a kidney transplant). (Cooper, Langone Testimony;

DXM-0563; DXM-0570; DXM-0576; DXM-0580; DXM-0587; DXM-0591; DXM-0593; DXM-0599; DXM-0603; DXM-0607.)

3. Myfortic is enteric-coated. As such, the active ingredient in Myfortic is absorbed in the small intestine, not the stomach. (Cooper, Langone Testimony; DXM-0563; DXM-0570; DXM-0576; DXM-0580; DXM-0587; DXM-0591; DXM-0593; DXM-0599; DXM-0603; DXM-0607.)

4. CellCept is not enteric-coated. As such, the active ingredient in CellCept is absorbed in the stomach. (Cooper, Langone Testimony.)

5. Beginning in or around May 2009, generic forms of CellCept, known as mycophenolate mofetil ("MMF"), became available on the market. (Berry, Rindini, Cooper, Langone Testimony.)

6. More than ten manufacturers have distributed versions of MMF pills since in or around May 2009. These various versions of MMF pills come in multiple sizes, shapes and colors. (Cooper, Langone Testimony.)

7. Myfortic was available only in brand form until in or around early 2014. (Cooper, Langone Testimony.)

8. Transplant surgeons and nephrologists ("transplant doctors") prescribe Myfortic, CellCept and MMF. (Cooper, Langone Testimony.)

9. Patients with kidney disease typically wait years on a transplant waiting list, while undergoing dialysis, to receive a kidney. Once a patient receives a kidney transplant and is able to cease dialysis, the patient's immune system begins a process of attempting to reject the implanted kidney. To combat that rejection process, nearly all kidney transplant patients are prescribed a mycophenolic acid ("MPA"), along with many other drugs designed to ensure the

success of the transplant. Myfortic and CellCept (and their generic formulations) are the only drugs on the market that are part of the MPA class of products. (Cooper, Langone Testimony.)

10. Transplant surgeons and nephrologists—highly educated and credentialed physicians—decide which MPA medication a kidney transplant patient will be prescribed. Those physicians make prescribing decisions based on what is in the patients' best interests. (Cooper, Langone Testimony). The transplant centers with whom transplant physicians are affiliated are ranked and evaluated for purposes of funding (including by government healthcare programs) based on patient outcomes. (Cooper Testimony.)

11. To protect the transplanted kidney—that is, patient outcomes—transplant recipients generally must adhere to their prescribed MPA regimen for as long as their kidney transplant lasts. Patients with lower rates of adherence to MPA have higher rates of kidney rejection, which can result in the loss of the transplanted kidney and even the loss of life. (Cooper, Langone Testimony.)

12. Factors impacting patients' adherence to MPA therapy include gastrointestinal ("GI") side effects (such as diarrhea and acid reflux) and pill confusion related to generic medications, such as MMF. With the availability of multiple forms of a generic product, like MMF, patients may experience variations from refill to refill in the size, shape and color of their pill, which may cause confusion. That confusion is compounded in the case of a kidney transplant patient, whose therapeutic regimen typically consists of numerous other medications. (Cooper, Langone, Young Testimony.)

13. Some transplant physicians prefer a branded MPA product to a generic MPA product because they are concerned about pill confusion. (Cooper, Langone, Young Testimony.)

14. Some transplant physicians prefer a branded MPA product to a generic MPA product because they believe that generic products do not contain consistent amounts of the immunosuppressive agent. (Cooper, Langone, Klintmalm Testimony.)

15. Some patients taking CellCept experience GI effects, including nausea, vomiting, constipation, diarrhea, ulceration and bleeding. (Cooper, Langone, Klintmalm Testimony.)

16. To alleviate some of those GI effects, some CellCept patients take proton pump inhibitors ("PPIs")—some of which are available only by prescription and some of which can be purchased "over the counter" without a prescription. (Cooper, Langone Testimony.)

17. In 2012, the FDA asked Roche to change CellCept's label to include a warning regarding a drug interaction between PPIs and CellCept. (DXM-0596.) In June 2012, CellCept's label was changed to state, among other things, that "[c]oadministration of PPIs" and CellCept "reduce[s] the exposure to mycophenolic acid (MPA)." (DXM-0595.)

18. Myfortic's label does not include a warning regarding a drug interaction between PPIs and Myfortic. In fact, Myfortic's label states that "[a]dministration of a pantoprazole," which is a type of PPI, "at a dose of 40 mg twice daily for 4 days to healthy volunteers did not alter the pharmacokinetics of a single dose of Myfortic." (DXM-0607.)

19. Specialty pharmacies are uniquely positioned to become aware of drug interactions patients might be experiencing, such as those between PPIs and CellCept, because transplant patients often purchase all of their medications from a single specialty pharmacy. (Niebanck, Thompson Testimony.)

20. Because PPIs are available over the counter or prescribed by a physician other than a transplant doctor, transplant doctors are often not aware that patients taking CellCept are

also taking a PPI unless it is brought to their attention by a patient or a pharmacy. (Cooper, Langone, Thompson Testimony.)

21. Specialty pharmacies are also uniquely positioned to learn of certain side effects patients might be experiencing and become aware of certain financial issues, like co-pay considerations between medications. (Berry, Niebanck, Sleath, Thompson Testimony.)

Novartis's Contracts with Specialty Pharmacies Regarding Myfortic

22. It is common in the healthcare industry for pharmaceutical manufacturers, such as Novartis, to enter into discount contracts with pharmacies, including specialty pharmacies. (Fein Testimony.)

23. Since 2004, Novartis has entered into written contracts ("Myfortic SP Contracts") with certain specialty pharmacies regarding Myfortic. Pursuant to the Myfortic SP Contracts, the Myfortic Contracted SPs were eligible to receive discounts and rebates from Novartis in connection with their dispenses of Myfortic. (DXM-0390; DXM-0456; NPCSP00003492 DXM-0402; NPCSP00004562 DXM-0414.)

24. Novartis has had direct contracts for Myfortic discounts and rebates with the following specialty pharmacies: Amber Enterprises, Inc. d/b/a Amber Pharmacy, Apothecary by Design LLC, Avella of Dear Valley, Inc. d/b/a Avella Specialty Pharmacy, formerly known as the Apothecary Shops, Armada Health Care, Bryant's Pharmacy & Health Care Center, Caremark LLC, Damer & Cartwright Pharmaceutical, Inc., Diplomat Specialty Pharmacy, Echo Pharmacy, F&M Specialty Pharmacy, Inc., Kerr Health Long Term Care, LLC, Kilgore's Medical Pharmacy, Kings Pharmacy, LLC, Livingston Infusion Care. Inc., d/b/a Discover Rx Infusion & Specialty Pharmacy, also known as Qualitas Special Pharmacy Services, Medical Center Pharmacy, Ascend Specialty Pharmacy Services, Inc., PMO Specialty Pharmacy, ProCare

Pharmacy LLC, , d/b/a Pharmacare Pharmacy Inc., Transcript Pharmacy, Inc., and Twenty-Ten Prescription Pharmacy, Inc. In addition, the following specialty pharmacies were eligible to receive discounts and rebates for Myfortic only through Novartis's contract with Armada Health Care LLP ("Armada"), a group purchasing organization ("GPO"): BioScrip, Inc., Walgreens Co. d/b/a Chroniscript, a Walgreens Pharmacy, Colonia Natural Pharmacy, Cornerstone Pharmacy, Kings Park Slope, Inc. d/b/a/ Kings Super Pharmacy, O'Steen's Specialty Mail Order Pharmacy, Precision Rx Specialty Solutions, RIL Drug, Total Care Rx, Inc., formerly known as UniRx, Wal-Mart Specialty Pharmacy and Walgreens Specialty Pharmacy (collectively, the "Myfortic Contracted SPs"). (DXM-0520; DXM-0198; DXM-0328; DXM-0346; DXM-0456; DXM-0440; DXM-0524; DXM-0445; DXM-0481; DXM-0527; DXM-0390; DXM-0512; DXM-0516; DXM-0499; DXM-0454; DXM-0509; DXM-0506; DXM-0402; DXM-0408.)

25. Novartis also had a contract with Baylor Healthcare System ("Baylor") that included Myfortic discounts ("Baylor Contract"). (DXM-0534; DXM-0267.)

26. The Myfortic Contracted SPs are specialty pharmacies. (Bryant, Morrissey, Osbon Testimony.)

27. The Myfortic Contracted SPs and Baylor have dispensed Myfortic to kidney transplant patients. (Bryant, Dillon, Foster, Morrissey, Osbon, Wong Testimony.)

28. The Myfortic SP Contracts provided that the Myfortic Contracted SPs would, among other things, provide "enhanced specialty pharmacy services" including assisting patients with "reimbursement, counseling, and disease management services including . . . drug therapy management, insurance verification and coverage assistance (including refill reminders and direct Medicaid billing), side effect management, quality of life counseling, disease education and information disbursement." (DXM-0390; DXM-0456; DXM-0402; DXM-0414.)

29. The discounts in the Myfortic SP Contracts and the Baylor Contract took the form of a percentage discount off of the price of Myfortic paid by the specialty pharmacy. (DXM-0390; DXM-0456; DXM-0414; DXM-0534; DXM-0267.)

30. The rebates in the Myfortic SP Contracts took the form of market share rebates. Per the market share rebates outlined in the contracts, if the Myfortic Contracted SP met the market share threshold listed in the contract on sales of Myfortic, it would receive from Novartis the rebate amount outlined in the contract that was associated with that particular market share threshold. (DXM-0390; DXM-0456; DXM-0402; DXM-0414.)

31. The only "remuneration" at issue in the Myfortic case is the rebates and discounts reflected in the Myfortic SP Contracts and the Baylor Contract. (See Government's Second Amended Complaint, August 28, 2014, ECF No. 231.)

32. All rebates and discounts Novartis paid to the Myfortic Contracted SPs and Baylor fall squarely within the statutory exception and the regulatory safe harbor of the AKS. 42 U.S.C. § 1320a-7b(b)(3)(A); 42 C.F.R. § 1001.952(h)(3).

33. By its terms, the AKS does not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A); *see, e.g., U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003); *United States v. Shaw*, F. Supp. 2d 103, 114 (D. Mass. 2000).

34. Each Myfortic SP Contract and the Baylor Contract sets out all of the terms and conditions related to the base discounts and market share rebates. In addition, the Myfortic SP Contracts and the Baylor Contract require the pharmacies to disclose the discounts and rebates to

the Government as required by law. The Myfortic SP Contracts and the Baylor Contract also require the pharmacies to "comply with the requirements of the federal and state anti-kickback statutes, including without limitation, 42 U.S.C. 1320a-7b and the reporting requirements thereunder . . ." and to "reflect the value of discounts and rebates submitted to Federal Healthcare Programs on cost reports and claims submitted to Federal Healthcare Programs." (DXM-0390; DXM-0456; DXM-0402; DXM-0414; DXM-0534; DXM-0267.)

35. In addition to this statutory exception for discounts and other price reductions, the AKS does not apply to "any payment practice specified by the Secretary" of Health and Human Services in applicable regulations. 42 U.S.C. § 1320a-7b(b)(3)(E). These regulations provide a safe harbor to entities such as Novartis that "offer" discounts to buyers. 42 C.F.R. § 1001.952(h)(3); *see U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc*., No. 13CV3779, 2014 WL 6750786, at *7-8 (S.D.N.Y. Dec. 1, 2014) (Cote, J.). Novartis complied with all the requirements of the safe harbor. It is Plaintiffs' burden to demonstrate that the discounts and rebates provided by Novartis did not fall under either the statutory exception or the regulatory safe harbor, and it cannot prove either. *See U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc*., No. 13CV3779, 2014 WL 6750786, at *9 (S.D.N.Y. Dec. 1, 2014) (Cote, J.).

36. Novartis informed the Myfortic Contracted SPs and Baylor of their obligations to report and provide information about the discounts and rebates, and Novartis refrained from doing anything that would impede the Myfortic Contracted SPs and Baylor from meeting their obligations under the safe harbor. (Rindini, Niebanck Testimony; DXM-0390; DXM-0456; DXM-0402; DXM-0414; DXM-0534; DXM-0267.)

37. Even assuming Novartis had a reasonable but incorrect interpretation of the statutory exception or regulatory safe harbor with respect to Myfortic, such technical failure to

comply was not knowing. "[U]nresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant's interpretation of the governing law is reasonable." U.*S. ex rel. Finney v. Nextwave Telecom, Inc*., 337 B.R. 479, 488 (S.D.N.Y. 2006) (McMahon, J.) (internal quotation marks omitted).

38. Each Myfortic SP Contract and the Baylor Contract reflect the entirety of the agreement between Novartis and the Myfortic Contracted SP and Baylor, respectively. (Niebanck, Rindini Testimony.)

39. Each Myfortic SP Contract and the Baylor Contract also contain an integration clause providing that the Contract reflects the "entire agreement" of the parties. (DXM-0390; DXM-0456; DXM-0402; DXM-0414; DXM-0267.)

40. There are no terms, conditions or other obligations binding upon either party that are not reflected in the written Myfortic SP Contracts and Baylor Contract. (Niebanck, Rindini Testimony.)

41. At no point did Novartis enter into any "side agreement" or extra-contractual agreement with any of the Myfortic Contracted SPs or Baylor requiring the pharmacy to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic to prescribers. (Bryant, Dillon, Kilgore, Morrissey, Niebanck, Osbon, Rindini, Wong Testimony.)

42. At no point did any Myfortic Contracted SP or Baylor commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate contract from Novartis or more favorable terms in the discount/rebate contract. (Bryant, Dillon, Kilgore, Morrissey, Niebanck, Osbon, Rindini Wong Testimony.)

43. Novartis did not select pharmacies for Myfortic contracts based on any purported "influence" pharmacies had over transplant physicians and/or centers. Instead, Novartis contracted with pharmacies it believed would be able to properly serve the needs of kidney transplant patients to whom Myfortic was prescribed. In addition, Novartis contracted with pharmacies that served transplant patients from transplant centers whose physicians favored and prescribed Myfortic. (Rindini, Niebanck Testimony.)

44. Absent discounts and rebates from Novartis on Myfortic, the Myfortic Contracted SPs and Baylor could not afford to carry and dispense Myfortic to patients, particularly those whose medications were paid for by Medicare Part B because reimbursement is based on an average sales price that reflects discounts. (Gaier, Bryant, Osbon Testimony.)

45. By providing discounts and rebates to the Myfortic Contracted SPs and Baylor, Novartis wanted to ensure that those pharmacies serving kidney transplant patients could afford to carry and dispense Myfortic to patients whose physicians had prescribed it. (Rindini Testimony.)

46. Novartis's payment of rebates to the Myfortic Contracted SPs—and conversely, Novartis's failure to pay a rebate to a pharmacy—was based solely on whether the market share thresholds in the contract were met. Payment of the rebates did not take into account any other factor or any other activities undertaken by the pharmacy. (Wong, Kilgore, Dillon, Osbon and Bryant Testimony.)

47. There is no evidence that Novartis terminated or failed to extend a contract to a pharmacy, or changed the terms of a Myfortic SP Contract or a Baylor Contract because the pharmacy did not "promise" to promote or market Myfortic to prescribers, or advocate for conversion to, or increased use of, Myfortic to prescribers.

48. Pharmacies' implementation of doctors' decisions to switch patients from CellCept or MMF to Myfortic often involves administrative action by the pharmacies, including outreach to and education of patients regarding the switch and verification of patients' insurance coverage. Those activities, in certain instances, are burdensome and costly for the pharmacy. (Sachs, Antley Testimony.)

49. During the relevant period, some transplant doctors chose to switch patients to Myfortic from CellCept (or MMF) for clinical reasons, including Myfortic's side effect profile as compared to CellCept—particularly as to GI issues—CellCept's interaction with PPIs, doctors' negative perceptions of the clinical attributes of generics and doctors' interest in avoiding confusion that may result if patients on generic CellCept receive varying formulations of MMF from dispense to dispense. Doctors would become aware of these issues, at times, from specialty pharmacies. (Klintmalm, Thompson Testimony; DXM-0213; DXM-0549; DXM-0106.)

50. In addition, during the relevant period, some transplant doctors chose to switch patients to Myfortic from CellCept or MMF because of financial considerations impacting patients, such as lower co-pays on Myfortic than CellCept. Doctors would become aware of these issues, at times, from specialty pharmacies. (Kilgore, Bryant, Young Testimony; DXM-0549; DXM-0565.)

Role of Physician

51. Transplant doctors exercise control over the medications patients take to prevent rejection of a transplanted kidney. Transplant doctors do not abdicate their clinical judgment to specialty pharmacies. (Klintmalm, Young Testimony.)

52. A specialty pharmacy is not able to dispense Myfortic to a patient without a valid prescription from a physician for Myfortic. (Sleath Testimony.)

53. A specialty pharmacy is not able to switch a patient from CellCept or MMF to Myfortic—or from CellCept or MMF to Myfortic—without a valid prescription from a physician for Myfortic. (Sleath Testimony.)

54. It is appropriate for a doctor to switch from CellCept or MMF to Myfortic a patient who is taking CellCept or MMF and experiencing GI side effects. (Cooper, Langone Testimony.)

55. It is appropriate for a doctor to switch from CellCept (or MMF) to Myfortic a patient who is taking CellCept (or MMF) and a PPI. (Cooper, Langone Testimony.)

56. It is appropriate for a doctor to switch a patient from CellCept to Myfortic where that will save the patient money. (Cooper, Langone Testimony.)

57. Novartis did not attempt improperly to influence the judgment of physicians to prescribe Myfortic. (Rindini, Niebanck Testimony.)

Cost of Myfortic

58. Prior to October 2009, the Average Sales Price ("ASP") (see 42 C.F.R. 414.804) for Myfortic was lower than the ASP for CellCept. (Gaier Testimony.)

59. Medicare Part B provides reimbursement for immunosuppressive products for transplant patients during the first 36 months after a transplant. (Gaier, Cooper Testimony.)

60. Both the published Average Wholesale Price ("AWP") and Wholesale Acquisition Cost ("WAC") were lower for Myfortic than for branded CellCept from 2004 through 2013. (Gaier Testimony.)

Baylor Healthcare System

61. Baylor Healthcare System ("Baylor") operates the Annette C. and Harold C. Simmons Transplant Institute ("Baylor Transplant"), which includes transplant centers in Dallas and Fort Worth, Texas. Baylor also operates an outpatient pharmacy in Dallas called Baylor Medical Plaza ("Plaza"). (Klintmalm, Foster Testimony.)

62. In February 2010, Novartis and Baylor entered into a contract that provided a Myfortic discount to Baylor's transplant centers and Plaza. (DXM-0534.)

63. At no point did Plaza commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate from Novartis. Baylor's written contract with Novartis represented the entirety of the parties' agreement. (Foster Testimony.)

64. Dr. Goran Klintmalm has served as the Chief and Chairman of Baylor Transplant since 1985. Dr. Klintmalm is not only the final authority on which medications are prescribed to his patients, he is also the final authority on which medications Baylor chooses for its transplant patients generally. (Klintmalm, Foster Testimony.)

65. In December 2009, Dr. Klintmalm decided that all kidney transplant patients at Baylor—both new patients and patients previously transplanted—would be prescribed Myfortic instead of CellCept. Dr. Klintmalm's decision was based on concern that CellCept was causing significant GI side effects for patients. These side effects were less prevalent among patients taking Myfortic. Dr. Klintmalm's decision was also motivated by concern that CellCept patients would receive generic versions of the product, which he considered inferior to the branded form. (Klintmalm Testimony; DXM-0106.)

66. Dr. Klintmalm made the decision to convert all of Baylor's CellCept patients to Myfortic in consultation with transplant surgeons and nephrologists at Baylor. This decision was based solely on the physicians' clinical judgment. Financial factors, such as discounts from and a contract with Novartis, played no role in this decision. (Klintmalm Testimony.)

67. Baylor's pharmacists, including pharmacists at Plaza, were not involved in Dr. Klintmalm's decision to prescribe Myfortic instead of CellCept to kidney transplant patients. (Klintmalm, Foster Testimony.)

68. Baylor's pharmacists, including pharmacists at Plaza, did not influence Dr. Klintmalm's decision to prescribe Myfortic instead of CellCept to kidney transplant patients. (Klintmalm, Foster Testimony.)

69. Prior to Dr. Klintmalm's decision, Baylor pharmacists had been negotiating a contract with Novartis, but those negotiations had failed and the parties did not reach an agreement. Moreover, at the time Dr. Klintmalm decided to convert Baylor patients to Myfortic, Baylor and Novartis were not even discussing a potential Myfortic agreement. (DXM-0270; DXM-0106; DXM-0108.)

70. Baylor and Novartis did negotiate and agree to a contract in February 2010, providing Baylor with a Myfortic discount. This agreement was reached months after Dr. Klintmalm's decision had been made and Baylor had already begun to convert its CellCept patients to Myfortic. (Klintmalm Testimony; DXM-0534; DXM-0106.)

71. In October 2010, Baylor's transplant centers and Plaza became eligible for 340B pricing, which qualified Baylor for a 60% discount on Myfortic—a significantly larger discount than Baylor had received from Novartis under the February 2010 agreement. This change rendered moot Baylor's February 2010 agreement with Novartis. (DXM-0262.)

Bryant's Pharmacy and Healthcare Center

72. Bryant's Pharmacy and Healthcare Center ("Bryant's") is a specialty pharmacy located in Batesville, Arkansas. Bryant's is owned by Steven Bryant, a licensed pharmacist in Arkansas. From 2004 through 2013, Bryant's received discounts and rebates from Novartis related to Myfortic—either through a direct contract with Novartis or through Novartis's contract with Armada. (Bryant Testimony; DXM-0456.)

73. At no point did Bryant's commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate from Novartis. Each of Bryant's written contracts with Novartis (both direct and through Armada) represented the entirety of the parties' agreement. (Bryant Testimony.)

74. The majority of Myfortic prescriptions filled by Bryant's between 2004 and 2013 were for patients from Baptist Hospital ("Baptist") in Little Rock, Arkansas. Dr. Scott Young, a nephrologist, serves as the Medical Director of Transplantation at Baptist. In addition to being the final authority in determining what medications are prescribed to his patients, Dr. Young also plays an important role in determining the medications prescribed by other physicians at Baptist. (Young Testimony.)

75. When determining the appropriate MPA to prescribe to his patients and to include on Baptist's protocol, Dr. Young strongly considered drug pricing. He frequently preferred drugs that, in addition to being safe and effective, would save money for patients and payors—including Medicare and Medicaid. Dr. Young also strived to save money for the Arkansas Kidney Disease Commission ("AKDC"), a program established and paid for by the state of Arkansas to help patients pay for expenses relating to kidney disease. Dr. Young serves as a

member of the AKDC and has been involved with the program for more than eight years. (Young Testimony.)

76. Myfortic was generally less expensive for payors (including Medicare and Medicaid) and patients than CellCept from 2004 through 2009. (Bryant Testimony.)

77. In or around 2006, Dr. Young began prescribing Myfortic to his kidney transplant patients instead of CellCept, and Baptist likewise generally began prescribing Myfortic instead of CellCept to kidney transplant patients. This decision was motivated largely by Myfortic being less expensive than CellCept at that time. (Young Testimony.)

78. Dr. Young's decision to prescribe Myfortic instead of CellCept resulted in an increase in the amount of Myfortic prescriptions Bryant's was filling. This increase ultimately led to Bryant's having a high percentage of Myfortic utilization as opposed to CellCept. (Bryant Testimony.)

79. In 2009, after generic versions of CellCept became available, Dr. Young began prescribing generic CellCept to his new kidney transplant patients. This decision was motivated by Dr. Young's concern over cost, as generic CellCept was less expensive than Myfortic. Dr. Young did not switch to generic CellCept all of his patients already receiving Myfortic because he was concerned that this might cause anxiety for the patients and because he recognized that other Arkansas doctors were reluctant to prescribe generic transplant medicines. As to the existing Myfortic patient population, Dr. Young made case-by-case assessments regarding what medication would be appropriate for each patient. (Young Testimony; DXM-0103; DXM-0104.)

80. Dr. Young's decision to maintain existing Myfortic patients on Myfortic after the introduction of generic CellCept and not to convert all of those patients to generic CellCept was

not based on, or influenced by, any statement or recommendation by Bryant's. (Young Testimony.)

Kilgore's Medical Pharmacy

81. Kilgore's Medical Pharmacy ("Kilgore's") is a specialty pharmacy located in Columbia, Missouri. Kilgore's is owned by a group of partners including Robert Kilgore, Kilgore's founder and former President, and William Morrissey, Kilgore's current President. From 2004 through 2013, Kilgore's had a contract with Novartis through which Kilgore's received from Novartis discounts and rebates on Myfortic. (Kilgore, Morrissey Testimony; DXM-0390.)

82. At no point did Kilgore's commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate from Novartis. Kilgore's written contract with Novartis represented the entirety of the parties' agreement. (Kilgore, Morrissey Testimony.)

83. Since 2002, Kilgore's has served as the exclusive pharmacy of the Missouri Kidney Program ("MoKP"), a state program created to "promote the physical and mental well-being of eligible Missouri Residents with Chronic Kidney Disease." MoKP pays for kidney transplant medications for patients of limited financial means. MoKP requires that patients receive their outpatient medications, including MPA, from Kilgore's. (DXM-0610; Kilgore Testimony.)

84. Kilgore's shares half of all rebates it receives from pharmaceutical manufacturers, including Novartis, with MoKP. (Kilgore, Morrissey Testimony; DXM-011.)

85. In 2004, MoKP gave Myfortic preferred status on its formulary because Myfortic was less expensive than CellCept, it believed patients on Myfortic would suffer from fewer GI

side effects as compared to patients on CellCept and Myfortic's pill was 30% smaller than CellCept's and therefore "may be easier for patients to swallow". At that time, MoKP sent a letter to Missouri doctors urging them to prescribe Myfortic to MoKP beneficiaries and asked Kilgore's to "formalize" the conversion process by sending a fax to the doctor when a MoKP patient was prescribed CellCept so that the doctor could change the prescription to Myfortic. (Kilgore Testimony; DXM-0549.)

86. It is Kilgore's practice to alert physicians when it learns that a patient is taking two drugs that could adversely interact. Kilgore's communicates with prescribers about drug-drug interactions on a daily basis. (Morrissey Testimony.)

87. In or around 2010, Kilgore's became aware of a drug-drug interaction between CellCept and PPIs. After determining that this drug interaction could significantly impact patients, Kilgore's sent faxes to prescribers informing them of patients receiving CellCept (or generic CellCept) and a PPI and the potential adverse interaction between those two drugs. The physicians would then decide whether to continue to prescribe CellCept to each relevant patient or to change the patient's prescription to Myfortic. Kilgore's did not decide which MPA would be prescribed. (Morrissey Testimony.)

88. Novartis's Myfortic discounts played no role in Kilgore's decision to inform prescribers about CellCept's interaction with PPIs. Kilgore's decision was prompted by legitimate clinical concerns, and Kilgore's believed that failure to provide this information to physicians would have been "negligent". (Morrissey Testimony.)

89. In addition, Novartis did not seek to, nor did it, extract any commitment from Kilgore's that Kilgore's would send faxes to prescribers about the CellCept-PPI interaction in order to obtain or maintain a Myfortic discount contract. (Morrissey, Thompson Testimony.)

Transcript Pharmacy

90. Transcript Pharmacy, Inc. is a pharmacy based in the Jackson, Mississippi area that serves kidney transplant patients from several transplant centers, including Tulane University hospital. Clifton Osbon, a Registered Pharmacist, is the President of Transcript. (Osbon Testimony.)

91. At no point did Transcript commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate from Novartis. Transcript's written contract with Novartis represented the entirety of the parties' agreement. (Osbon Testimony; DXM-0402.)

92. In 2006 and 2007, Transcript received discounts and rebates on Myfortic from Novartis through the Armada contract. In 2011, Novartis and Transcript entered into a direct contract for Myfortic, through which Transcript could receive rebates on sales of Myfortic. Transcript's written contract with Novartis represented the entirety of the parties' agreement. (DXM-0504; DXM-0513.)

93. Physicians at the transplant centers whose patients filled their MPA prescriptions at Transcript preferred Myfortic. Specifically, Dr. Sander Florman at Tulane had decided to switch patients from CellCept to Myfortic because Myfortic was less expensive and resulted in fewer GI effects than CellCept. Dr. Florman's decision to switch patients to Myfortic occurred years before Novartis and Transcript entered into the direct contract for Myfortic. (DXM-0213.)

94. Transcript did not influence in any way Dr. Florman's decision to switch patients to Myfortic. (Osbon Testimony.)

95. During contract negotiations with Novartis, the owner of Transcript claimed that he would work to switch patients away from Myfortic if he did not receive a contract for

Novartis for Myfortic. Such claims were simply bluster, in which the owner admittedly was "overstating [his] influence" and "posturing." (Osbon Testimony.)

96. Prior to entering into the 2011 contract with Novartis regarding Myfortic, Transcript was dispensing Myfortic at a loss. (Osbon Testimony.)

97. Transcript sought, and Novartis provided, the 2011 rebate contract so that Transcript could afford to carry and dispense Myfortic and "quit losing money." (Osbon Testimony.)

Twenty Ten Specialty Pharmacy

98. Twenty Ten Specialty Pharmacy ("Twenty Ten") is owned by Louis Wong and is located in Los Angeles, California. From 2004 through 2012, Twenty Ten received discounts and rebates from Novartis related to Myfortic—either through a direct contract with Novartis or through Novartis's contract with Armada. (Wong, Sachs, Antley Testimony; DXM-0408).

99. At no point did Twenty Ten commit to promote or market Myfortic to prescribers, or in any way advocate for conversion to, or increased use of, Myfortic by prescribers, in exchange for a discount or rebate from Novartis. Twenty Ten's written contracts with Novartis represented the entirety of the parties' agreement. (Wong, Sachs, Antley Testimony.)

100. Twenty Ten dispensed MPA to a substantial percentage of the transplant patients who received their kidney transplants from Los Angeles transplant centers, including UCLA, USC, Cedars-Sinai and St. Vincent. (Sachs Testimony.)

101. Los Angeles transplant physicians were early adopters of Myfortic, generally preferring to prescribe Myfortic over CellCept because of the clinical differences between the two medications. Some of the transplant physicians in the Los Angeles area began to prefer

Myfortic as early as 2004, when Myfortic was approved by the FDA. This preference applied to newly transplanted as well as existing kidney transplant patients. (Sachs, Antley Testimony.)

102. Between 2004 and 2013, Novartis's discounts and rebates to Twenty Ten enabled Twenty Ten to carry and dispense Myfortic to patients whose doctors had prescribed the drug without Twenty Ten incurring a financial loss on those prescriptions. (Sachs Testimony.)

103. In 2009, some Los Angeles physicians began moving additional patients from CellCept to Myfortic because they believed that generic MPA, numerous forms of which were becoming available for CellCept, was inferior to branded MPA. (Antley Testimony.)

104. This resulted in an influx of patients to Twenty Ten for whom Myfortic would be prescribed instead of CellCept. At the time, Twenty Ten pharmacy was dispensing the vast majority of the Myfortic that physicians were prescribing. (Antley Testimony.)

105. To effectuate the physicians' decisions to move a patient from CellCept to Myfortic, Twenty Ten would need to perform a substantial amount of burdensome and time-consuming administrative work, including patient coverage verification, patient education on the new medication, side effect counseling and monitoring for drug-drug interactions and adverse events. (Sachs, Niebanck Testimony.)

106. Later, some Los Angeles physicians were concerned about CellCept patients who might be taking a PPI and indicated that those patients should be on Myfortic. To help effectuate physicians' clinical decisions in favor of Myfortic (including performing the necessary administrative activities in connection with those decisions), Novartis executed a discount and rebate contract with Twenty Ten in 2011 that provided for discounts and rebates. (Sachs, Niebanck Testimony.)

The Statutory Exception and Regulatory Safe Harbor Apply

107. All rebates and discounts Novartis offered and paid to the Myfortic Contracted SPs and Baylor fall squarely within the statutory exception and the regulatory safe harbor of the AKS. 42 U.S.C. § 1320a-7b(b)(3)(A), (E); 42 C.F.R. § 1001.952(h)(2).

108. By its terms, the AKS does not apply to "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program". 42 U.S.C. § 1320a-7b(b)(3)(A); *see, e.g., U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003).

109. In addition to this statutory exception for discounts and other price reductions, the AKS does not apply to "any payment practice specified by the Secretary" of Health and Human Services in applicable regulations. 42 U.S.C. § 1320a-7b(b)(3)(E). These regulations provide a safe harbor to entities such as Novartis that sell to buyers. 42 C.F.R. § 1001.952(h)(2)(iii)(B); *see U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc.*, No. 13CV3779, 2014 WL 6750786, at *7-8 (S.D.N.Y. Dec. 1, 2014) (Cote, J.). Novartis complied with all the requirements of the statutory exception and the regulatory safe harbor. (Rindini, Niebanck Testimony.) It is Plaintiffs' burden to demonstrate that the discounts and rebates provided by Novartis did not fall under either the statutory exception or the regulatory safe harbor, and it cannot prove either. *See U.S. ex rel. Fox Rx, Inc. v. Dr. Reddy's Inc.*, No. 13CV3779, 2014 WL 6750786, at *9 (S.D.N.Y. Dec. 1, 2014) (Cote, J.).

110. Consistent with Congress's rationale for the AKS discount exception, the Myfortic SP discounts and rebates benefit patients and have reduced the cost of Myfortic to payors, including government healthcare programs. (Gaier Testimony.)

111. Even assuming that Novartis had a reasonable but incorrect interpretation of the statutory exception or regulatory safe harbor with respect to Myfortic, such technical failure to comply was not knowing. "[U]nresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant's interpretation of the governing law is reasonable." *U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479, 488 (S.D.N.Y. 2006) (McMahon, J.) (internal quotation marks omitted).

Novartis's Actions Were Not Unlawful

112. In order to prevail on their claims under 31 U.S.C. §§ 3729(a)(1)(A) & (B) and their state law analogues, Plaintiffs must establish that (1) Kilgore's, Bryant's, Baylor, Transcript and Twenty Ten made a false or fraudulent claim or statement, (2) Novartis knew that the claim or statement was false or fraudulent, (3) Novartis knowingly caused the false or fraudulent claim or statement to be made to Plaintiffs, (4) the false or fraudulent claim or statement was material to Plaintiffs' decision to pay, and (5) as a result of the false or fraudulent claim or statement, Plaintiffs suffered damages. 31 U.S.C. §§ 3729(a)(1)(A) & (B), 3731(d); *U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 86 (2d Cir. 2012); *U.S. ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 432, 440 (S.D.N.Y. 1999) (McMahon, J.).

113. Plaintiffs allege that the claims or statements submitted by Kilgore's, Bryant's, Baylor, Transcript and Twenty Ten in connection with reimbursements for Myfortic were false or fraudulent because Novartis and those pharmacies were violating the AKS while the pharmacies were certifying compliance with the AKS. If the statutory discount exception and

regulatory safe harbor do not apply, Plaintiffs must prove that Novartis (1) knowingly and willfully (2) offered or paid remuneration (3) to induce those pharmacies to recommend purchasing or ordering Myfortic (4) that would be reimbursed by Plaintiffs' government health care programs. 42 U.S.C. § 1320a-7b(b)(2)(B).

114. To prove that the pharmacies violated the AKS, Plaintiffs must also establish, to the extent an exception or safe harbor does not apply, that Kilgore's, Bryant's, Baylor, Transcript and Twenty Ten (1) knowingly and willfully (2) solicited or received remuneration (3) in return for recommending purchasing or ordering Myfortic (4) that would be reimbursed by Plaintiffs' government health care programs. 42 U.S.C. § 1320a-7b(b)(1)(B).

115. In order to show that Novartis knew that the certifications of compliance with the AKS that those five pharmacies submitted to Medicaid and Medicare were false, Plaintiffs must show that Novartis either actually knew that the certifications of compliance with the AKS were false or acted in deliberate ignorance or reckless disregard of whether the certifications of compliance with the AKS were false. 31 U.S.C. § 3729(b)(1). As part of that burden, Plaintiffs must prove that Novartis actually knew that there was a violation of the AKS or acted in deliberate ignorance or reckless disregard of whether there was a violation of the AKS. *See Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

116. Novartis did not violate the AKS or any of its state law counterparts. 42 U.S.C. § 1320a-7b(b)(2)(B).

117. Novartis was not seeking "to induce" the pharmacies to recommend to doctors that they purchase or order Myfortic, and the pharmacies were not seeking to recommend Myfortic "in return for" remuneration. *See United States v. LaHue*, 261 F.3d 993, 1003 (10th Cir. 2001); *United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012). There was no

"kickback" within the meaning of the AKS. To the extent that Novartis offered or paid any remuneration to the pharmacies, it was in the form of contractual discounts and market share rebates, and those discounts and rebates are protected by the AKS exception and safe harbor regulations. Novartis never intended to induce the pharmacies to recommend to doctors that they prescribe Myfortic because of any influence of that remuneration over the pharmacies' independent professional judgment.

118. The pharmacies did not perceive the discounts and market share rebates from Novartis as an inducement to recommend to doctors that they prescribe Myfortic over CellCept or MMF. (Kilgore, Osbon, Bryant's Testimony.) In fact, the pharmacies could not have improperly influenced, and did not improperly influence, any doctor to prescribe Myfortic over CellCept or MMF. (Kilgore, Morrissey, Niebanck, Rindini, Klintmalm, Cooper, Langone Testimony.)

119. Novartis was not seeking to induce the pharmacies to "recommend" Myfortic as that term is used in the AKS. Novartis knew that the specialty pharmacies did not prescribe or "recommend" Myfortic for purposes of the AKS.

Novartis Did Not Violate the FCA or Any State Analogues

120. Causes of action under the FCA or any state equivalents are predicated on an underlying violation of the AKS, and, without a violation of the AKS, there can be no FCA or other state law cause of action because the certifications of compliance with the AKS were not false. *U.S. ex rel. Kester v. Novartis Pharms. Co*. (*Novartis IV*), 41 F. Supp. 3d 323, 335 (S.D.N.Y. 2014).

121. Even assuming a violation of the AKS, no violation of the FCA exists because Plaintiffs cannot prove that any act by Novartis caused claims to be made that would not have

been made absent any kickbacks. *See* 42 U.S.C. § 1320a-7b(g); *U.S. ex rel. Chen v. EMSL Analytical, Inc.*, No. 10-7504, 2013 WL 4441509, at *18 (S.D.N.Y. Aug. 16, 2013); *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-1806, 2013 WL 1346022, at *3-*4 (E.D.N.Y. Apr. 3, 2013); *U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003).

122. Doctors prescribed Myfortic irrespective of anything Novartis or the specialty pharmacies said or did. (Klintmalm, Cooper, Langone Testimony.) Plaintiffs cannot prove that any doctor recommended a particular purchase or order of Myfortic that was not consistent with his or her independent clinical judgment. *Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1362 (11th Cir. 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010). Plaintiffs cannot prove that Novartis's conduct "result[ed] in" any "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a) or any state equivalents. (Gaier Testimony.)

123. Plaintiffs cannot establish that any particular individual at Novartis with authority to act on behalf of the Company had sufficient knowledge of the alleged kickback scheme to constitute institutional knowledge necessary to an FCA violation. *See U. S. v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010).

124. Plaintiffs cannot prove any conspiracy claims because Plaintiffs are unable to show an underlying actionable claim. Moreover, Plaintiffs cannot prove that Novartis and any other entity had an agreement and specific intent to defraud the government. *See Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672-73; *U.S. ex rel. Wuestenhoefer v. Jefferson*, No. 4:10-CV-00012, 2015 WL 226026, at *25 (N.D. Miss. Jan. 16, 2015).

Damages

125. Plaintiffs cannot establish liability under the FCA or state laws because they cannot prove the essential element of damages. 31 U.S.C. § 3731(d). (Gaier Testimony.)

126. There is no evidence that the United States or state governments sustained damages "because of the act[s] of" Novartis, as required under 31 U.S.C. § 3729(a)(1). Even assuming for purposes of argument that the pharmacies and Novartis violated the AKS, the United States and state governments would have made the same reimbursement payments absent such violations. (Gaier Testimony.)

127. For any allegedly fraudulent Myfortic Medicare or Medicaid claim reimbursement, if those claims would have been submitted and reimbursed even had there been no alleged kickbacks, then there are no damages because the United States and state governments did not pay any money as a result of the allegedly false claim. (Gaier Testimony.)

128. For any Medicare or Medicaid claim for which brand-name CellCept would have been purchased instead of Myfortic had there been no alleged kickbacks, there are no damages because the United States and state governments did not pay any money for Myfortic by reason of the allegedly false claim above what it would have paid for CellCept. (Gaier Testimony.)

129. Pharmacies typically earned substantially larger profit margins dispensing generic CellCept than branded Myfortic (even after discounts and rebates) based on the difference between payor reimbursement and the costs of those medications. This difference gives the pharmacies a strong economic incentive to dispense generic CellCept instead of Myfortic. Thus, after the introduction of generic CellCept in 2009, the Myfortic discounts and rebates would not have been able to induce pharmacies to seek to improperly influence doctors to prescribe Myfortic instead of generic CellCept. (Gaier Testimony.)

130. Moreover, for any Medicare or Medicaid claims for which generic CellCept would have been purchased instead of Myfortic had there been no alleged kickbacks, the amount of damages should be limited to the difference between the United States' (or state

government's) payment for Myfortic and what the United States' (or state government's) payment would have been for generic CellCept. (Gaier Testimony.)

131. Even if Plaintiffs demonstrate liability, the number of statutory penalties owed would be limited to the number of fraudulent acts committed by Novartis itself. United States v. Bornstein, 423 U.S. 303, 313 (1976). If any statutory penalties are awarded, they should be in the lowest amount possible under the FCA or state equivalent statutes for all of the reasons that Novartis argues it should not be found liable under the AKS, FCA and state equivalent statutes. (Gaier Testimony.)

132. Plaintiffs cannot prove that Plaintiffs' injuries were proximately caused by the acts or omissions of Novartis; if injuries exist at all, they were the result of intervening or superseding causes. (Gaier Testimony.)

133. Plaintiffs' claims fail because they have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the complaints. (Gaier Testimony.)

134. To the extent Plaintiffs obtain or obtained recovery in any other proceeding or settlement predicated on the same factual allegations, Plaintiffs cannot obtain a double recovery against Novartis. (Mem. & Order ("*Novartis VI*") at 22, Sept. 4, 2014, ECF No. 234.)

135. Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs, through the Medicare and Medicaid programs have reimbursed specialty pharmacy providers for dispensing Myfortic to Medicare and Medicaid beneficiaries after the filing of the complaints.

136. Plaintiffs' claims violate Novartis's rights under the Due Process and Ex Post Facto Clauses of the United States Constitution and the Constitutions of the states, insofar as

Plaintiffs seek to impose liability retroactively for conduct that was not prohibited when it took place. *Landgraf v. USI Film Products*, 511 U.S. 244, 266 (1994).

137. Plaintiffs' claims fail because they are too remote and speculative to form the basis for relief. *See Clapper v. Amnesty Int'l USA*, 133 S.Ct. 1138, 1160-61 (2013).

V. ISSUES TO BE TRIED

Exjade

1. Whether Novartis knowingly and willfully offered or paid any remuneration, including any patient referrals or any rebates, to Accredo, BioScrip, and/or US Bioservices to induce any of these specialty pharmacies to recommend the purchase or order of Exjade by any patient.

2. Whether the rebates Novartis offered to those pharmacies for Exjade are subject to the statutory/regulatory discount safe harbor. *See* 42 U.S.C. § 1320a-7b(b)(3)(A) & (E); 42 C.F.R. § 1001.952(h).

3. Whether Novartis knowingly caused any false or fraudulent claim for Exjade to be presented by any of these specialty pharmacies to Medicare or Medicaid for payment.

4. Whether Novartis knowingly caused the making or the use of any false statement or record material to a false or fraudulent Medicare or Medicaid claim for Exjade.

5. Whether Novartis conspired with Accredo, BioScrip and/or US Bioservices to violate the False Claims Act.

6. If Novartis violated the False Claims Act (including as a co-conspirator), the amounts of damages that Plaintiffs are entitled to recover under the False Claims Act.

7. If Novartis violated the False Claims Act (including as a co-conspirator), the number of false or fraudulent claims presented in connection with the alleged Exjade kickback scheme.[5]

8. Whether Novartis is liable for the Plaintiffs' state statutory or common law claims and, if so, the amounts of damages.

Myfortic

1. Whether Novartis knowingly and willfully offered or paid any remuneration to one or more specialty pharmacy to induce the specialty pharmacy to recommend the purchase or order of Myfortic.

2. Whether the performance rebates Novartis offered to specialty pharmacies for Myfortic are subject to the statutory/regulatory discount safe harbor. *See* 42 U.S.C. § 1320a-7b(b)(3)(A) & (E); 42 C.F.R. § 1001.952(h).

3. Whether Novartis knowingly caused any false or fraudulent claim or statement for Myfortic to be presented by a specialty pharmacy to Medicare or Medicaid for payment.

4. Whether Novartis knowingly caused the making or the use of any false statement or record material to a false or fraudulent Medicare or Medicaid claim for Myfortic.

5. Whether Novartis conspired with Kilgore's, Bryant's, Baylor, Twenty Ten, and/or Transcript to violate the False Claims Act.

6. If Novartis violated the False Claims Act (including as a co-conspirator), the amounts of damages that Plaintiffs are entitled to recover under the False Claims Act.

[5] Defendant does not agree that this is an issue to be tried. It suggests the following issue instead: If Novartis is liable, the specific number of Novartis's own acts that Plaintiffs have proved caused a violation of the False Claims Act.

7. If Novartis violated the False Claims Act (including as a co-conspirator), the number of false or fraudulent claims presented in connection with the alleged Myfortic kickback scheme.[6]

VI. PLAINTIFFS' EXHIBITS

1. Attached as Exhibit A is Plaintiffs' Exhibit List.

2. Plaintiffs reserve the right to add, delete, or modify the exhibits designated below, including the right to offer any exhibits on Defendant's exhibit list at trial.

VII. DEFENDANT'S EXHIBITS

1. No exhibit not listed below may be used at trial except (a) for cross-examination purposes or (b) if good cause for its exclusion from the pretrial order is shown.

2. Attached as Exhibit B is Novartis's Exhibit List. Novartis reserves the right to supplement or modify its Exhibit List as a result of the production of documents by Plaintiffs after the close of discovery. Novartis further reserves the right to use at trial exhibits listed on Plaintiffs' Exhibit List.

VIII. STIPULATIONS AND OBJECTIONS WITH RESPECT TO EXHIBITS

A. Stipulations

None.

B. Objections

See Plaintiffs' and Defendant's respective Exhibit Lists. Any objections not set forth therein or herein will be considered waived absent good cause shown.

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[6] Defendant does not agree that this is an issue to be tried. It suggests the following issue instead: If Novartis is liable, the specific number of Novartis's own acts that Plaintiffs have proved caused a violation of the False Claims Act.

1. Plaintiffs' Objections

Plaintiffs object to the introduction and use of all documents marked as exhibits during the depositions unless and until objections concerning authenticity and admissibility are resolved. Furthermore, Plaintiffs' objections to Defendant's trial exhibits assume that the parties will reach a stipulation regarding the business records exception as applied to documents produced in this litigation. Plaintiffs reserve the right to object to Defendant's exhibits on hearsay or authenticity grounds if such stipulation is not reached.

2. Novartis's Objections

Novartis's objections to Plaintiffs' Exhibits are reflected on Plaintiffs' Exhibit List, attached as Exhibit A. Novartis's objections are based on certain reasonable assumptions about the purposes for which Plaintiffs will use their trial exhibits, and Novartis reserves the right to supplement their objections based on the particular use or uses Plaintiffs attempt to make of each exhibit at trial.

Novartis reserves the right to seek to preclude the use of any of Plaintiffs' intended trial exhibits which should have been, but were not, produced before the end of fact discovery.

IX. PLAINTIFFS' WITNESSES

The witnesses listed below may be called at trial. No witness not identified in one or both parties' witness list shall be permitted to testify in either party's case in chief absent good cause shown.

A. Plaintiffs' Witness List

Witness	Live / Video*
Fact Witnesses	
Boehm, Rainer (Novartis)	Live (Will Call)
Brandt, William (Novartis)	Live (Will Call)
Chee, Emily (Novartis)	Live (Will Call)
Davis, Steven (Novartis)	Live (Will Call)
Dunn, Keary (Novartis)	Live (Will Call)

Witness	Live / Video*
Goldfarb, Steven (Novartis)	Live (Will Call)
Hinshaw, William (Novartis)	Live (Will Call)
Jolley, Rebecca (Novartis)	Live (Will Call)
Lazala, Virginia (Novartis)	Live (Will Call)
McGee, Elizabeth (Novartis)	Live (Will Call)
Metro, Joseph (Novartis OC)	Live (Will Call)
Mignogna, Michael (Novartis)	Live (Will Call)
Morton, Marion (Novartis)	Live (Will Call)
Ng, Peter (Novartis)	Live (Will Call)
Niebanck, James (Novartis)	Live (Will Call)
Pochtar, Paul (Novartis)	Live/Video (Will Call)
Rindini, Rob (Novartis)	Live (Will Call)
Sachs, Melinda (Novartis)	Live (Will Call)
Stillwell, Matthew (Novartis)	Live (Will Call)
Thomas, Lincy (Novartis)	Live (Will Call)
Thompson, Loren (Novartis)	Live (Will Call)
Martin, William (Accredo)	Live (Will Call)
Watson, Stacy (Accredo)	Live (Will Call)
Abramowitz (Bioscrip)	Live (Will Call)
Carney, Wendalyn (Bioscrip)	Live (Will Call)
Corvese, Russell (Bioscrip)	Live (Will Call)
Murray, Lois (Bioscrip)	Live (Will Call)
Palmer, Summer (Bioscrip)	Live (Will Call)
Hernandez, Michael (US Bioservices)	Live/Video (Will Call)
Bryant, Steven (Bryant's Pharmacy)	Live (Will Call)
Osbon, Clifton (Transcript Pharmacy)	Live (Will Call)
Antley, Kimberly (Novartis)	Video (Will Call)
Berry, Rick (Novartis)	Video/Live (Will Call)
Padron, Frank (Novartis)	Video (Will Call)
Creason, Amy (Accredo)	Video (Will Call)
Donofrio, Rhonda (Accredo)	Video (Will Call)
Jackson, Milissa (Accredo)	Video (Will Call)
Wiley, Clara (Accredo)	Video (Will Call)
Williams, Janice (Accredo)	Video (Will Call)
Deno Sara (Bioscrip)	Video (Will Call)
Edwards, Nikki (Bioscrip)	Video (Will Call)
Efries, Carolyn (Bioscrip)	Video (Will Call)
Englehardt, Elizabeth (Bioscrip)	Video (Will Call)
Friedman, Scott (Bioscrip)	Video (Will Call)
Houston, Ja'neer (Bioscrip)	Video (Will Call)
Jessee, Quintin (Bioscrip)	Video (Will Call)
Mymo, Lisa (Bisocrip)	Video (Will Call)

Witness	Live / Video*
Ness, Stacey (Bioscrip)	Video (Will Call)
Sack, Nicholas (Bioscrip)	Video (Will Call)
Scott, Brian (Bioscrip)	Video (Will Call)
Smith Richard (Bioscrip)	Video (Will Call)
White, Bonita (Bioscrip)	Video (Will Call)
30(b)(6) (Bioscrip)	Video (Will Call)
Garcia, Angela (US Bioservices)	Video (Will Call)
Grady, Kevin (US Bioservices)	Video (Will Call)
Hayman, Janice (US Bioservices)	Video (Will Call)
Lisby, Sophie (US Bioservices)	Video (Will Call)
30(b)(6) (US Bioservices)	Video (Will Call)
30(b)(6) (Lash)	Video (Will Call)
Kilgore, Robert (Kilgore's Pharmacy)	Video (Will Call)
Morrissey, William (Kilgore's Pharmacy)	Video (Will Call)
Wong Louis (Twenty-Ten Pharmacy)	Video (Will Call)
Young, Scott (Baptist Health)	Video (Will Call)
Bhattacharya, Sheila (Novartis)	Live (May Call)
Bian, Jie (Novartis)	Live (May Call)
Bissinger, Kristin (Novartis)	Live (May Call)
Bloomquist, Christin (Novartis)	Live (May Call)
Chinn, Robert (Novartis)	Live (May Call)
Cline, David (Novartis)	Live (May Call)
Epstein, David (Novartis)	Live/Video (May Call)
Jones, Tony (Novartis)	Live (May Call)
Kothari, Shefali (Novartis)	Live (May Call)
Mandala, John (Novartis)	Live (May Call)
Nelson, Sherry (Novartis)	Live/Video (May Call)
Olsen, Kenneth (Novartis)	Live/Video (May Call)
O'Reggio, Kenneth (Novartis)	Live (May Call)
Weiner, Conna (Novartis)	Live (May Call)
Yoon, William (Novartis)	Live/Video (May Call)
Crockett, Phyllis (Accredo)	Live (May Call)
Holliday, Andrea (Accredo)	Live (May Call)
Parker, Josh (Accredo)	Live (May Call)
Accredo witness who signs contention interrogatories	Live (May Call)
Expert Witnesses	
Daniels, Charles E.	Live (Will Call)
Haddad, Amy M.	Live (Will Call)
Johnson, Cage	Live (Will Call)
Miller, Kenneth B.	Live (Will Call)
Rosenstein, Stan	Live (Will Call)

Witness	Live / Video*
Rosenthal, Meredith	Live (Will Call)
Tan, Henkie	Live (Will Call)
Hartstein, Marc	Live (Will Call)
Ranck, Andrew	Live (Will Call)
Rice, Cheri	Live (Will Call)
Shapiro, Jennifer	Live (Will Call)
FDA Witness	Live (Will Call)
Allen, Robin	Live (May Call)
Ault, Linda	Live (May Call)
Bilezikijian, Stephen	Live (May Call)
Hart, Carolyn	Live (May Call)
Karson, Samuel	Live (May Call)
Mazzone, Alfonzo	Live (May Call)
Sroka, Robin	Live (May Call)
Ware, Colin	Live (May Call)
State Medicaid Witnesses**	
Diane Furukawa (CA)	Live
Rodney Yamamura (CA)	Live
Shelley Silva (CA)	Live
Natasha Underwood (CA)	Live
Jess Sanford (CA)	Live
Chris Huang (CA)	Live
Linda Wiant (CA)	Live
David Ostrander (GA)	Live
Christy Klarman (GA)	Live
Mark Huston (IL)	Live
Debbie Helms (IL)	Live
Eric Watson (IL)	Live
Mark Slezewick (IN)	Live
Richard Walton (IN)	Live
Margaret M. Landers-Graves (IN)	Live
Emily Hancock (IN)	Live
Chris Johnson (IN)	Live
Athos Alexandrou (IN)	Live
Dixit Shah (MD)	Live
Craig Smalls (MD)	Live
Susan R. Steinberg (MD)	Live
Ashley Randall (MD)	Live
Linda Dietsch (MD)	Live
Mike Pereira (MD)	Live

Witness	Live / Video*
Trish M. O'Keefe (MI)	Live
B'leia Williams (NJ)	Live
Dianna Rosenheim (NJ)	Live
Janet Zachary-Elkind (NY)	Live
Neil McDonough (NY)	Live
Jonathan Bick (NY)	Live
Nancy Nesser (OK)	Live
Tom Simonson (OK)	Live
Stacey Hale (OK)	Live
Kerri Wade (OK)	Live
Jill Ratterman (OK)	Live
Kyle Janzen (OK)	Live
Justin Etchieson (OK)	Live
Tywanda Cox (OK)	Live
Rebecca Burton (OK)	Live
Ryan Freeman-Smith (OK)	Live
Della Gregg (OK)	Live
Chuck Agte (WA)	Live
Sandy Mitchell (WA)	Live
Ann Myers (WA)	Live
Cathie Ott (WA)	Live
Sonja Winkelman (WA)	Live
Kimberly Smithers (WI)	Live
Patrick Healey (WI)	Live
*Where a witness is listed as likely to testify by "Video" the video deposition testimony to be used is identified in Exhibit C to this Joint Pretrial Order.	
** It may not be necessary to call these witnesses if the parties are able to reach certain evidentiary stipulations.	

Plaintiffs reserve the right to offer in its case in chief the testimony of any witness identified on Defendant's witness list either live or by video.

Plaintiffs also reserve the right to call rebuttal witnesses.

B. Plaintiffs' Deposition Designations

Plaintiffs' Deposition Designations are attached as Exhibit C, which also contains Defendant's objections and counter-designations and Plaintiffs' additional fairness counter-designations.

C. Defendant's Reservations/Objections to Plaintiffs' Deposition Designations

Novartis reserves the right to use deposition testimony designated by Plaintiffs or to call at trial witnesses listed by Plaintiffs.

Novartis objects to the use at trial of deposition testimony contrary to the requirements of Fed. R. Civ. P. 32(a), including but not limited to deposition testimony given by witnesses who are available to testify in person. Novartis's objections and counter-designations to Plaintiffs' deposition designations are shown in Exhibit C. Novartis reserves the right to amend or withdraw its counter-designations in response to any modifications by Plaintiffs of their designations. Furthermore, in certain instances Novartis has counter-designated testimony in response to Plaintiffs' designation of certain testimony that Novartis believes to be objectionable. To the extent that Novartis's objections are sustained and Plaintiffs' designated testimony is excluded, Novartis reserves the right to withdraw the testimony it designated in response to the excluded testimony, and further reserves the right to object to any use by Plaintiffs of such Novartis counter-designations.

Novartis's objections are based on certain reasonable assumptions about the purposes for which Plaintiffs will use the designated testimony, and Novartis reserves the right to supplement its objections to the extent that Plaintiffs' actual use of the designated testimony differs from those assumptions. Novartis also objects to the admissibility of any testimony designated by Plaintiffs that relates to any trial exhibit that is ruled inadmissible. Novartis objects to the use by

Plaintiffs of any non-testimonial attorney colloquy as part of any designations (e.g., attorney objections at a deposition).

Novartis further objects to the use at trial of any of Plaintiffs' proposed "counter counter" designations. The parties' agreement with respect to the exchange of designations and objections does not permit the service of such designations. Furthermore, Plaintiffs served these designations only several hours before the joint pretrial order was due to the Court, depriving Novartis of the opportunity to object to these designations.[7]

X. DEFENDANT'S WITNESS LIST

A. Defendant's Witnesses

Exjade

Witness	Live/By deposition	Objections
Rainer Boehm	Live	
Emily Chee	Live	
Elizabeth Engelhardt	Live	
Adam Fein	Live	
Eric Gaier	Live	
Steven Goldfarb	Live	
Ludovico Guarini	Live	
Rebecca Jolley	Live	
Elizabeth McGee	Live	

[7] Plaintiffs dispute Novartis's objection concerning Plaintiffs' proposed "counter-counter" designations to deposition testimony. These designations are "fairness" designations under Federal Rule of Civil Procedure 32(a)(6), which provides, "If a party offers in evidence only part of a deposition, an adverse party may require the offeror to introduce other parts that in fairness should be considered with the part introduced[.]"

Witness	Live/By deposition	Objections
Joseph Metro	Live	
Michael Mignogna	Live	
Sherry Nelson	Live	
Ellis Neufeld	Live	
Peter Ng	Live	
August Salvado	Live	
Betsy Sleath	Live	
Ryan Szanto	Live	
Lincy Thomas	Live	
BioScrip, Inc.	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Russel Corvese	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Amy Creason	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Sara Deno	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Rhonda Donofrio	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

Witness	Live/By deposition	Objections
Carolyn Efries	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Scott Friedman	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Angela Garcia	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Janice Hayman	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Michael Hernandez	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Quintin Jessee	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
David Kester	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Sophie Lisby	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Lois Murray	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

Witness	Live/By deposition	Objections
Lisa Mymo	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Stacey Ness	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Frank Padron	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Brian Scott	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Karen Tadlock	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Clara Wiley	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

Myfortic

Witness	Live/By deposition	Objections
Matthew Cooper	Live	
Adam Fein	Live	
Sander Florman	Live	Plaintiffs object to Sander Florman, on the ground that Defendant never named him in its previous disclosures, as required by Fed. R. Civ. P. 26(a).

Witness	Live/By deposition	Objections
Eric Gaier	Live	
Ron Del Gaudio	Live	Plaintiffs object to Ron Del Gaudio because Novartis's Rule 26(a) disclosure gives his contact information as King's Pharmacy. Because King's Pharmacy is no longer part of the Plaintiffs' contentions in this case, Mr. Del Gaudio's testimony would tend to confuse the issues, mislead the jury, and waste time.
Gordon Ingle	Live	
Anthony Langone	Live	
Jesus Leal	Live	
James Niebanck	Live	
Robert Rindini	Live	
Melinda Sachs	Live	
Betsy Sleath	Live	
Loren Thompson	Live	
Kimberly Antley	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Rick Berry	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

Witness	Live/By deposition	Objections
Steve Bryant	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
William Dillon	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	Plaintiffs object to the playing of William Dillon's deposition, which concerns only PMO Pharmacy—a pharmacy that is no longer part of Plaintiffs' contentions in this case, Mr. Dillon's testimony would tend to confuse the issues, mislead the jury, and waste time.
John Foster	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Robert Kilgore	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Goran Klintmalm	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
William Morrissey	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	
Clifton Osbon	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

Witness	Live/By deposition	Objections
Scott Young	By deposition (see Exhibit D for Novartis's designations, Plaintiffs' objections, Plaintiffs' counter-designations and Novartis's objections thereto)	

B. Defendant's Deposition Designations

Defendant's Deposition Designations are attached as Exhibit D, which also contains Plaintiffs' objections and counter-designations.

C. Plaintiffs' Reservations and Objections to Defendant's Deposition Designations

Plaintiffs object to the use of the deposition testimony of any witness as inadmissible hearsay if that witness appears to provide testimony in person.

Plaintiffs object to the introduction and use of all documents marked as exhibits during the depositions unless and until objections concerning authenticity and admissibility are resolved.

Plaintiffs reserve the right to present any deposition testimony designated in their affirmative deposition designations in response to Novartis' deposition designations and hereby incorporate Plaintiffs' affirmative designations in our counterdesignations.

Plaintiffs object to the designation of any testimony discussing or referring to evidence that is not admitted into evidence, including testimony discussing or referring to any deposition exhibits that are not admitted into evidence and any testimony covered by in limine orders excluding evidence.

XI. RELIEF SOUGHT

Plaintiffs seek damages for Medicare and Medicaid's expenditures on all claims that were tainted by kickbacks. Specifically:

1. In connection with the alleged Exjade scheme the pharmacies submitted 126,802 claims to Medicare and Medicaid and obtained $492,905,758 in reimbursement.

2. In connection with the alleged Myfortic scheme, the pharmacies submitted 39,209 claims to Medicare and Medicaid, and obtained $14,589,787in reimbursement.

3. Under the FCA, Plaintiffs are entitled to treble damages and a civil penalty of $5,500 to $11,000 for each false claim.

Dated: June 29, 2015

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